Invitation to Bid

for

Alabama Medicaid

Pharmacy

Clinical Support

Bid #08-X-2192281
Alabama Medicaid Agency
May 2008

Section I Introduction to Procurement

1.1 General Requirements

The Alabama Medicaid Agency, hereafter called Medicaid, an Agency of the State of Alabama, solicits bids to perform clinical support services for the Medicaid Pharmacy Program under the provisions of the Code of Alabama, 1975, Section 41-16-20, et seq. as amended Section 41-22-1, et seq.

The successful bidder, hereafter called Contractor, shall be responsible for performance of all duties contained within this Invitation to Bid (ITB) for the amount of compensation quoted in bidder's response to this ITB. Bids shall state a firm and fixed administration price.

Medicaid will contract with a consultant to provide clinical and specified administrative support for the pharmacy program. Medicaid will maintain quality control through the utilization of its Pharmacy and Therapeutics (P&T) Committee. Additionally, the Contractor will not be allowed to restrict the provider network or mandate mail-order services. The Contractor will be required by the State to operate under all provisions of the Omnibus Budget Reconciliation Act (OBRA) 1990 and the Social Security Act. State regulatory authority is derived from the Code of Alabama 1975 and the Alabama Administrative Code.

1.2 Bidder Qualifications

The successful bidder must demonstrate a high level of expertise in pharmacy clinical support to include extensive experience in preferred drug list administration and clinical review. The necessary experience must have been within the last three years.

The successful bidder must meet the following minimum requirements:

1. Licensed to do business in the state of Alabama.
2. Licensed to do business for a minimum of three years.
3. Submit the original bid and five hard copies and one electronic copy of the bid on CD in Word 6.0 or higher format.
4. Provide all required documentation as specified by the ITB.
5. Submit bid for time period covered by the ITB.
6. Submit proof of a performance bond in the amount equal to two months payment.
7. Submit bid guarantee for five thousand dollars ($5,000).
8. Submit curriculum vitae for required personnel.
9. Assure through documented work plans the avoidance of real or perceived conflicts of interest.
10. Demonstrate the ability to secure and retain professional staff to meet contract requirements.
11. Provide personnel who are not involved in pharmaceutical detailing activities for any pharmaceutical company.
12. Submit price sheet with firm and fixed price.
13. Sign and notarize page one of the ITB.

14. Submit a brief overview of the history and structure of company, as well as a brief description of the organization's overall capabilities.
15. Submit a minimum of three references—at least one must be from a state Medicaid agency or other government program. Include client name, contact name, title, telephone number, contract type, size and duration.
16. Submit a work plan detailing ability to perform duties as outlined in this ITB to be at a minimum, the quality of reviews used in CY 2007 and 2008.
17. Certify that neither it nor its principals is presently debarred, suspended, proposed for debarment, declared ineligible, or voluntarily excluded from participation in this contract by any federal department or agency.
18. The Contractor, including its subsidiaries and affiliates, has not unilaterally and willfully terminated any previous review contract prior to the end of the contract term with a state or federal government and has not had a contract terminated by a state or federal government for cause, prior to the end of the contract term, within the last five years;

1.3 Disclosure Statement

The following information must be provided by prospective bidders:

1. Are you an independent entity or a subsidiary or division of another company? If not an independent entity, describe the organization linkages and the degree of integration/collaboration between the organizations.
2. List and explain any financial relationships with any pharmaceutical manufacturers.
3. If not owned by a pharmaceutical manufacturer, is your organization strategically aligned with a pharmaceutical manufacturer? If yes, describe the organization and linkages and the degree of integration/collaboration between the organizations.
4. Provide in detail specific processes and procedures by which the Contractor will assure the avoidance of any conflict or appearance of conflicts of interest.
5. Disclose all organizations, states, and health plans for which your organization is currently administering or has previously administered pharmacy benefits within the last three years. Provide organization names, contact persons, address, phone number and fax number.

1.4 Disclosure of Information

Contractor and Medicaid shall agree that all information, records, and data collected in connection with this contract, shall be protected from unauthorized disclosure. Access to such information shall be limited by Contractor and Medicaid to persons or agencies conducting authorized business relating to the administration of this contract, including, but not limited to, Health and Human Services (HHS) and Centers for Medicare and Medicaid Services (CMS). All disclosures are subject to the confidentiality restrictions expressed in this contract, State and Federal law, and regulations.

1.5 Background

The Alabama Medicaid Agency is the single state agency responsible for administering the Medicaid program in Alabama. The Medicaid program is partially funded with federal revenues provided through CMS, which establishes rules and regulations for the program and approves the state plan under which the state program operates.

Since the formulary expansion of OBRA 1990, Medicaid expenditures in Alabama for outpatient drugs have escalated from approximately $60 million in 1990 to over $700 million in Fiscal Year

2007. This dramatic change is directly related to the broad coverage mandated by OBRA 90, the increase in recipient enrollment and the increase in the costs of covered medications. Medicaid has aggressively sought to address pharmacy issues through the implementation of various programs with a clinical focus. In addition to the implementation of cost saving programs such as coverage for over-the-counter medications, a prescription brand limit and a state Maximum Allowable Cost (MAC) program, Medicaid has focused on programs that foster safe, appropriate and effective drug therapy. These programs include retrospective Drug Utilization Review (DUR), prospective DUR, provider education/academic detailing, prior authorization and the mandatory Preferred Drug Program and listings (PDL).

In accordance with Alabama Act No. 2003-297, Alabama Medicaid began implementation of a mandatory Preferred Drug Program effective November 2003. The Preferred Drug List (PDL) is composed of preferred brands, generics and covered over-the-counter (OTC) products of targeted and reviewed classes of drugs. Non-preferred agents for the classes reviewed remain covered but require prior authorization.

As of the writing of this ITB, Skeletal Muscle Relaxants, Antidepressants, Narcotic Analgesics, Platelet Aggregation Inhibitors, Anxiolytics, Hypnotic/Sedatives, Antihypertensives, Antihyperlipidemics, Agents for ADHD, Cardiac Agents, Triptans, Estrogens, Respiratory Agents, Intranasal Corticosteroids, Alzheimer Agents, Diabetic Agents, Skin and Mucous Membrane Agents, Proton Pump Inhibitors, Anti-infective Agents (with certain exceptions), Antiemetics and Eye, Ear, Nose and Throat (EENT) Preparations have been implemented into the PDL. Medicaid is open to recommendations from Contractor as to drug classes or sub-classes appropriate for future PDL reviews.

Legislation mandates that Medicaid is to develop the PDL in coordination with the Pharmacy and Therapeutics (P&T) Committee. The P&T Committee is comprised of a minimum of five physicians and three pharmacists that are licensed to practice in the State of Alabama. This group meets a minimum of four times annually and more often if necessary. During CY200**7**, they met a total of four times to conduct business and a total of four meetings were held in CY200**6**. All meetings are held in Montgomery, AL at a designated location. Medicaid makes arrangements for all meeting rooms. The P&T Committee functions include advising Medicaid on prior authorization, PDL reviews and coverage determinations. For purposes of the PDL, they perform in-depth clinical reviews of targeted classes of drugs. The P&T Committee serves as an advisory panel and makes recommendations to Medicaid utilizing reviews provided by the Contractor. These recommendations are noted by written ballot, announced during the P&T meeting and are reflected in the meeting minutes.

1.6 Purpose

The purpose of this ITB is to competitively procure contractor services to provide clinical support services for the Pharmacy Program for the State of Alabama Medicaid Agency. The Program design reflects the components of the programs that are currently operational and are successful in providing quality accessible care. The inclusion of a clinical consultant is the

preferred mechanism to avail the Agency of expertise within the industry and will make the Medicaid Pharmacy Program more effective.

Contractor shall meet or exceed user needs identified in Section II of this ITB. Contractor shall meet or exceed defined deliverables and expectations included in this ITB in an acceptable form.

To help prospective bidders understand the Preferred Drug Program and bid requirements, Alabama Medicaid will make available upon request the following documents:

1. Proposal from the current Primary Contractor
2. Previous ITB
3. Samples of P&T Committee packets
4. Examples of Max Units List, Nutritional Lists and the PDL Reference Tool

Prospective bidders may contact the Contract Administrator, as listed below, to request copies of the above noted documents that are not available via Medicaid's website and to also submit questions for clarification regarding the ITB components. Questions of this nature need to be submitted no later than close of business 4/25/08. Copies of the materials are available at $.25 per page plus administrative time. Prospective bidders are encouraged to review these materials. **(Please note that items listed in 3 and 4 are available on Alabama Medicaid's website: www.medicaid.alabama.gov.)**

Written questions can be submitted to Medicaid in the following ways:
FAX (334) 353-7014
E-mail: **bakeba.thomas@medicaid.alabama.gov**
US Mail: Alabama Medicaid Agency
501 Dexter Avenue
P.O. Box 5624
Montgomery. AL 36104
Attention: Bakeba R. Thomas, Pharmacy Program

All questions must be submitted in writing and received by the deadline as specified in the Schedule of Activities. All times stated in this ITB are Central Time. All amendments and question and answer documents pertaining to this ITB will be distributed in writing via US mail and will be posted to the Agency web-site at **www.medicaid.alabama.gov.**

1.7 Schedule of Activities

The Contractor must begin providing services outlined in this ITB no later than **July 1, 2008**. In order to implement timely, the following milestones must be met:

Activity	***Date***
Invitation to Bid (ITB) issued	4/4/08
Deadline for questions for ITB	4/25/08 5:00 p.m.
Answers to Questions mailed/posted	5/02/08
ITB Bid Responses Due	5/16/08 5:00 p.m.
Open Bid Responses	5/21/08 10:00 a.m.
Contract Award Date	No later than 6/20/08
Contract Begin Date	7/01/08

1.8 Contract Administrator

The individual designated by this ITB to coordinate activities, resolve questions, monitor Contractor performance, ensure that all contract requirements are met, approve payments and be the Alabama Medicaid Agency contact for the Contractor is:

Bakeba R. Thomas
Alabama Medicaid Agency
Medicaid Administrator
P. O. Box 5624
501 Dexter Avenue
Montgomery, AL 36103-5624
(334) 353-4582 or (334) 242-5050
(334) 353-7014 FAX
Email: **bakeba.thomas@medicaid.alabama.gov**

Contractor will be notified of any change in Contract Administrator.

1.9 Subcontracting

The contract shall not be assigned without written consent of Medicaid. Contractor may subcontract for the professional services of clinical pharmacists or other personnel necessary for the completion and maintenance of this contract and for the performance of its duties under this contract with advance written approval of both the subcontracted function and the subcontractor by Medicaid. Subcontractors shall demonstrate the capability to perform the function to be subcontracted at a level equal or superior to the requirements of the contract relevant to the service to be performed. All subcontracts shall be in writing, with the subcontractor functions and duties clearly identified, and shall require the subcontractor to comply with all applicable provisions of this ITB. Contractor shall at all times remain responsible for the performance by subcontractors approved by Medicaid. Contractor's performance bond and Contractor's responsibility for damages shall apply whether performance or non-performance was by Contractor or one of its subcontractors. Medicaid shall not release Contractor from any claims or defaults of this contract which are predicated upon any action or inaction or default by any subcontractor of Contractor, even if such subcontractor was approved by Medicaid as provided above. Contractor shall give Medicaid notice in writing by registered mail of any action or suit made against Contractor by any subcontractor or vendor, which in the opinion of Contractor may result in litigation related in any way to this contract with the State of Alabama.

1.10 Headings and Titles

Any headings or titles used to help identify any part of this ITB or any contract upon which it is based are for reference purposes only and shall not be deemed as controlling the interpretation or meaning of any provision of this ITB or any contract upon which it shall be based.

1.11 Rights of Medicaid

This Invitation to Bid (ITB) does not commit the State to award a contract, or pay any costs incurred in the preparation of a proposal in response to this request. The Alabama Medicaid Agency reserves the right to reject all proposals and at its discretion may withdraw or amend this ITB at any time.

Alabama Medicaid may by written notice revise and amend the solicitation prior to the due date for the proposal. If, in the opinion of Medicaid, revisions or amendments will require substantive changes in proposals, the due date may be extended.

By submitting a proposal in response to this ITB, the proposing party grants to Medicaid the right to contact or arrange a visit in person with any or all of the bidder's clients. Upon selection of the Contractor, a letter of intent to the selected contractor will be issued. Unsuccessful bidders will be notified in writing after the award of the contract. **Information regarding the status of bidders' proposals will not be given via telephone.**

Section II Scope of Work

2.0 Scope of Work Overview

2.1 Pharmacy Program Clinical Support

The Contractor shall be responsible for the following programs:

Pharmacy and Therapeutic (P&T) Committee

Clinical Information and Reviews

1. Provide clinical information through the performance of clinical reviews of targeted classes or sub-classes of drugs to the Medicaid Pharmacy and Therapeutics (P&T) Committee and provide recommendations for inclusion/exclusion of reviewed drugs on the Medicaid Preferred Drug List. Review information provided to the P&T Committee shall be based on all relevant peer reviewed literature and studies, evidence based medicine and national guidelines. Also, rate each study or report that is presented to support recommendations. The rating is to be based on a nationally recognized scale (the contractor may pick the one that is most appropriate) which indicates the strength of the evidence for validity, clinical appropriateness, etc.

2. Provide clinical information through the performance of clinical reviews to the Medicaid P&T Committee of drugs new to the market as well as drugs that the P&T Committee believes should be re-evaluated. Provide recommendations for inclusion/exclusion of reviewed drugs on the Medicaid Preferred Drug List. Review information provided to the P&T Committee shall be based on all peer reviewed literature and studies, evidence based medicine and national guidelines . Also, rate each study or report that is presented to support recommendations. The rating is to be based on a nationally recognized scale (the contractor may pick the one that is most appropriate) which indicates the strength of the evidence for validity, clinical appropriateness, etc.

3. Recommend inclusion/exclusion of drugs to be considered in clinical reviews for P&T meetings based on AHFS or other classification, including but not limited to FDB coding.

4. Support the continued development and operation of the Medicaid Preferred Drug Program by providing current clinical research for review by the P&T Committee as well as providing qualified staff to present information to the P&T Committee.

5. Draft an agenda and meeting informational packets to include ballots for Pharmacy and Therapeutics (P&T) Committee meetings with Medicaid's approval. Draft materials are to be sent to Medicaid via electronic format and must be approved by Medicaid. A timeline for all drafts should be approved by Medicaid for each P&T review and must be followed by the Contractor.

6. Mail approved materials (informational packets, meeting agenda, etc) to all P&T members and necessary Medicaid staff. The materials are to be sent by Contractor via overnight mail and must be postmarked at least (2) two weeks prior to the meeting. There are currently nine (9) members of the P&T Committee. In addition, Medicaid requires ten (10) copies of the materials (a total of 19 hard copies will be needed). Copies

for Medicaid staff may be directed to PDL Administrator, Pharmacy Services. Meeting materials must also be supplied to Medicaid in electronic format for posting to the Medicaid web site. Versions should be sent to Medicaid on CD, hard copies and via email.

7. Provide clinical research, data and reviews to the P&T Committee and/or Medicaid regarding preferred drug reviews and drugs to be considered for prior authorization, overrides, or coverage issues as requested by Medicaid or the P&T Committee. Also, rate each study or report that is presented to support recommendations. The rating is to be based on a nationally recognized scale (the contractor may pick the one that is most appropriate) which indicates the strength of the evidence for validity, clinical appropriateness, etc.

8. Provide clinical information and utilization data based on state and national trends in prescribing and dispensing patterns regarding the need for drugs specified by the P&T Committee and/or Medicaid.

9. Provide clinical information and respond to questions from Medicaid designated Pharmacy staff in a timely and professional manner.

Committee and Meetings

10**.** Provide overview of clinical review packet information for each AHFS class reviewed to the P&T members at the Committee meetings.

11. Act as the recording secretary of all P&T Committee meetings and provide detailed and comprehensive minutes to Medicaid within (2) two weeks after the meeting for approval. A final copy is to be sent to Medicaid for sign-off upon completion and must be received by Medicaid within one week of receipt of approval by Medicaid.

12. Provide a written summary of P&T Meeting minutes for Alabama Medicaid's DUR Board.

13. Notify members of P&T Committee of meetings in coordination with Medicaid.

14. Receive, review and mail all qualified manufacturer comments to P&T members and Medicaid. Manufacturers are to be notified of any documents containing inappropriate information such as cost so that they can make arrangements for pickup.

15. Coordinate all requests for oral presentations by manufacturers at P&T meetings to include receipt of requests, receipt and review of presentation summaries, written record of sign in by presenters at meetings, receipt and review of handouts at P&T meetings and distribution to Medicaid and members.

16. Notify manufacturers of upcoming P&T reviews and maintain database of manufacturer contact information sheets.

17. Provide an electronic version of public notice of meeting and drug classes scheduled for review to Medicaid for posting to web site in accordance with timeline.

18. Send written notification to P&T members whose terms are expiring.

19. Send written notification to new members selected for the P&T Committee.

20. Maintain a listing of committee members and send an electronic version to Medicaid annually or upon update.

21. Conduct an orientation with all new members prior to first meeting to provide an orientation to the committee. These meetings are to be conducted with a designated Medicaid staff member.

22. Provide an electronic version of public notice of meeting and drug classes scheduled for review to Medicaid for posting to web site in accordance with timeline.

23. Respond to clinical appeals as related to the reviews for the P&T Committee meeting for the PDL. Responses should include any concerns or issues in the appeal from the manufacturer concerning the drug, information regarding any studies or clinical information that the manufacturer has presented, and give reason why it was or was not included in the review and why or why it does not change the recommendation. A final summary paragraph needs to state if the original recommendation presented in the review should stand as is or if it needs to be amended. It is the responsibility of the Contractor to respond to any appeals within the designated timeframe regarding information that the Contractor has presented even after the contract has expired.

Preferred Drug Program and Listings (PDL)

24**.** Compile a list for Medicaid approval of all products scheduled for PDL review and maintain all PDL lists by utilizing Medicaid's Decision Support System (DSS) and FDB and AHFS classes.

25. Recommend classes or sub-classes of drugs to Medicaid to be included in the Preferred Drug Program.

26. Provide projected cost savings for classes/sub-classes recommended for review for the PDL based on past medical claims data.

27. Make recommendations to Medicaid regarding operational policy and procedures for the Preferred Drug Program and pharmacy program policy and procedures as they relate to the scope of work of this ITB. Contractor is expected to utilize its expertise in the scope of this ITB to identify procedures that may improve current Medicaid policy.

28. Develop, maintain, and update internal and external criteria for those drugs that fall in the scope of the PDL, as well as when requested by Medicaid for those drugs currently on

prior authorization that fall outside the scope of the PDL. All criteria must be approved by Medicaid.

Drug Coverage Recommendations

29. Provide notification to Medicaid within one calendar week of First DataBank **(**FDB) notification of products new to the market that fall into a classification of drugs included in the scope of the Preferred Drug List or the Prior Authorization Program, override program, or coverage/non-coverage. Provide recommendations to include in review for PDL, Prior Authorization Program, override program, or coverage/non-coverage.

30. Review FDB Clinical and Editorial highlights on a weekly basis and make recommendations to the Agency on any needed actions.

31. Provide projected cost savings for potential edits/overrides/non-coverage for drugs and drugs classes that fall outside the scope of the PDL as requested by Medicaid.

32. Maintain and update the maximum unit list using methodology approved by Medicaid. This list should be updated on a routine basis according to a timeline approved by Medicaid. New drugs identified for the max unit list must be approved by or recommended by Medicaid. Currently, Medicaid max unit limits are based on FDB's GSN coding.

33. Maintain and update the covered nutritional list using methodology approved by Medicaid upon request.

34. Recommend drugs, based on clinical information, to be considered for prior authorization, override, or coverage to Medicaid through the P&T Committee or the Agency that fall into the following categories:

- Drugs with historical problems relative to physical and psychological dependency
- Drugs used for non-FDA approved indications or whose use is not supported by appropriately conducted and published, peer-reviewed medical research
- Drugs which require important diagnostic procedures be completed before the administration to maximize therapeutic benefits
- Drugs associated with special dosing, duration and/or administration requirements or considerations
- Drugs for which feedback is necessary to assist practitioners with treatment alternatives that may be just as effective, safe and less costly
- Drugs for which over-the-counter alternatives exists and are covered or could be covered by Medicaid
- Drugs with high cost or supply problems

2.1.1 Hemophilia Audit Program

History

Hemophilia is an inherited disease that prevents the blood from clotting properly. People with hemophilia have a deficiency of a blood protein, also called a "clotting factor," that is necessary to clot the blood and stop bleeding. One way to manage the disease is to administer blood factor replacement drugs to the patient. These factor replacement drugs are extremely costly, and are usually dispensed through specialty pharmacies. In a year's time (June 2006 to May 2007), the Agency spent $15.3 million on clotting factor replacement drugs for 74 Medicaid-eligible patients through the outpatient pharmacy program. The Agency currently has approximately 11 providers of blood clotting factors through the outpatient pharmacy program.

In January 2008, the Agency implemented a Hemophilia Standard of Care (SOC) to ensure all recipients receive a minimum standard of care and to remove inconsistencies in how the clotting factor is provided. The SOC requires that health care professionals providing hemophilia-related services must meet minimum hemophilia-related continuing education requirements each year, and follow a minimum standard on patient care and coordination. The SOC also outlines where the Agency (or its designated representative), to ensure clinically appropriate services are being given to hemophilia patients, shall monitor providers of blood clotting factors by prospective and retrospective audits, as well as a patient/family/caregiver satisfaction survey. The SOC can be found on our website in our Administrative Code Rule No. 560-X-16-.31 Hemophilia Management Standards of Care, or in Attachment I.

The Agency is including the hemophilia audit component of this program in this Clinical Contract; Contractor will act as our "designated representative" and shall be responsible for audit criteria development, audit procedures, notification to provider, and coordination to Agency regarding results from the audit. Contractor shall provide a Hemophilia Audit Coordinator to conduct and oversee audit activities. At the time of writing this ITB, the Agency has draft audit criteria for the Contractor to make recommendations before final approval. All auditing components must receive approval from Medicaid prior to their distribution.

Contractor Responsibilities

The following listing includes, but is not limited to, the responsibilities related to the hemophilia auditing component of this contract. At the time of writing of this ITB, the Agency has developed draft criteria components for various hemophilia audits, and anticipates one audit per year based on all blood clotting factor providers. Also, a subsequent audit per year based on recipient high utilizers of blood clotting factors. Contractor will be responsible for all hemophilia auditing components and must not proceed with any audit component without prior approval from Medicaid.

1. Conduct, at minimum, bi-annual retrospective audits on providers of blood clotting factor to ensure compliance with minimum standards of care guidelines, reimbursement methodology and Medicaid and State billing and BOP policy, dispensed dose assay, 24-hour call emergency support service, appropriate staff, emergency delivery of blood clotting factor

2. Conduct, at minimum, bi-annual retrospective audits on hemophilia patient assessment and follow up, educational materials offered and monthly case management follow-up

3. Conduct retrospective audits of notification of product recalls or withdrawals as needed or requested by Medicaid

4. Conduct, at minimum, bi-annual retrospective audits of quantity of blood clotting factor dispensed, the amount billed and invoice pricing submitted to Alabama Medicaid

5. Notify participating pharmacies of auditing procedures, to include requesting required documentation needed.

6. Mail approved materials to hemophilia providers and necessary Medicaid staff. The materials are to be sent by Contractor via certified mail and must be postmarked at least 30 days prior to the audit.

7. Report the outcome of each provider audit to the designated Alabama Medicaid representative.

8. Recommend to Alabama Medicaid's designated pharmacy staff those non-compliant pharmacy providers.

9. Utilizing the Agency Decision Support System (DSS), identify hemophilia providers to be audited, detailed patient specific claim information, and blood clotting factor reimbursement information to be used in the auditing procedures.

10. Draft audit procedures and hemophilia provider notifications. Draft materials are to be sent to Medicaid via electronic format and must be approved by Medicaid. A timeline for all drafts should be approved by Medicaid for each audit and must be followed by the Contractor. At the time of writing this ITB, the Agency has draft audit criteria for the Contractor to make recommendations before final approval.

11. Provide a Hemophilia Audit Coordinator to conduct and oversee auditing procedures. This person shall have a deep understanding of hemophilia, blood clotting factor delivery, and prescriptions/orders for these drugs. The Hemophilia Audit Coordinator may also serve as the Clinical Pharmacist.

12. Provide clinical information and respond to questions from Medicaid designated Pharmacy staff in a timely and professional manner.

13. Support the continued development and operation of the Medicaid Hemophilia Audit Program by providing current clinical research for review as well as providing qualified staff to present information to the fair hearing meetings held in Montgomery, AL.

14. Provide clinical information and utilization data based on state and national trends in prescribing and dispensing patterns regarding the need for blood clotting factor specified by Medicaid.

2.1.2 Reference Tools

In order to provide current in-depth clinical information, Contractor must have readily available access to the following:

1. CD-ROM/On-line/ hard copy databases
   - MedLine
   - Micromedex
   - Medscape
   - FDA (Food and Drug Administration)
   - NIH (National Institute of Health)
   - International Pharmaceutical Abstracts
   - The Formulary Information Exchange
   - Helix
   - New England Journal of Medicine
   - Physician's GenRx
   - Scientific American Medical Textbook
   - Mandell's Principles and Practices of Infectious Disease
   - Mayo Clinic Family Health Book
   - AHFS
   - PubMed
   - OVID
   - First DataBank
   - United States Pharmacopeia
   - Medical Usage Studies
   - Clinisphere/Facts & Comparisons
   - Drug Information Facts
   - Micromedex Redbook for Windows
   - Patient Drug Facts
   - Epocrates
   - Alabama Medicaid's Decision Support System (DSS)
2. Medical/Pharmacy and related journals, textbooks and newsletters such as
   - AHFS Drug Information
   - Annals of Internal Medicine
   - Annals of Pharmacotherapy
   - American Journal of Managed Care
   - Clinical Infectious Diseases
   - Clinical Microbiology Update
   - Critical Care Medicine
   - Disease-A-Month
   - Disease Management and Health Care Outcomes
   - Drug Benefit Trends
   - Drug Information Handbook
   - Drug Information Journals
   - Drugs
   - Drugs and Aging
   - Drug Safety
   - Drugs and Therapy Perspectives
   - Facts & Comparisons

- Healthcare Innovation
- HIV/AIDS Surveillance
- Infectious Disease Alert
- Internal Medicine Alert
- JAMA
- Journal of Managed Care Pharmacy
- Journal of Outcomes Management
- Lexicomp Drug Information Handbook
- New England Journal of Medicine
- New Products Bulletin
- Prescriber's Letter
- Medical Letters
- Pharmacist's Letter
- United States Pharmacopeia

2.2 Clinical Reviews

The Contractor will provide recommendations for classes to review for the PDL based on AHFS classification, and any new drugs that are eligible for review in the scope of the PDL. The Agency will provide the Contractor with the approved AHFS classes and new drugs for review. The Contractor will provide Medicaid with a list of drugs from Medicaid's drug file that fall into those AHFS classifications, and add/delete drugs that fall into/out of the particular AHFS classification(s) along with documentation to clinically support why those particular drugs need to be included/excluded from the review. The Contractor is also to provide recommendations on how to group/sub-group single entity versus combination products, what drugs are brand versus generic, and OTC versus legend. The Agency is to approve the first draft of the drug list and return to Contractor as defined in a timeline approved by Medicaid for each respective review. The Contractor is to provide the Agency with a "clean," approved, final drug list (to include all appropriate information as listed in Contractor Deliverables) as defined in a timeline approved by Medicaid for each respective review. Contractor is to obtain Medicaid approval prior to deviating from approved final list.

Reviews are to be developed and presented according to the AHFS classification system unless specified by Medicaid. Reviews are to be developed in a consistent format as agreed upon with Medicaid. Medicaid must approve the groups and subgroups by AHFS classification in which the Contractor intends to conduct and present the reviews. Contractor is to obtain Medicaid approval prior to deviating from the approved groupings and/or sub-groupings.

Reviews are to reference and discuss peer reviewed studies and publications relevant to the drugs under review. References are to be included in the review packets. All pertinent studies and clinical literature are to be reviewed by the Contractor and referenced in the reviews. Supporting documentation is to be available upon request by the P&T Committee or Medicaid. Also, rate each study or report that is presented to support recommendations. The rating is to be based on a nationally recognized scale (the contractor may pick the one that is most appropriate) which indicates the strength of the evidence for validity, clinical appropriateness, etc.
Contractor is to give an oral presentation of the reviews at the P&T Committee meeting. This presentation is to be made by a clinical pharmacist who is fully versed with the information

contained in the review and who is capable of entertaining questions from Committee members regarding findings and recommendations.

All reviews are to follow Medicaid policy.

2.3 Contractor Deliverables

Contractor is to provide all contract deliverables in a timely and professional manner in a format using a time line approved by Medicaid.

P&T Committee

Clinical Information and Reviews

1. Provide a packet to P&T members and Medicaid staff to include, clinical reviews, agenda, table of contents, and ballots for P&T Committee meetings in electronic format and hard copy as described in Section 2.1, item(s) 4, 5, 6 of this ITB. Each clinical review packet should be contained in a three ring binder and should be labeled and paginated accordingly. The P&T Committee is required to meet a minimum of four times per year.

2. Provide queries, using Medicaid's DSS, for drug lists for clinical reviews upon Medicaid's request to include information deemed appropriate by Medicaid but not limited to: NDC, brand name, generic name, manufacturer, manufacturer labeler code, strength, dosage form, Alabama specific generic indicator, OTC versus legend indicator as described in Section 2.1, item(s) 3.

3. Provide to Medicaid a response to clinical appeals on work conducted by the Contractor requested by manufacturers as a result of PDL or P&T reviews. These responses should be received by Medicaid within 30 days of the request. The response should contain clinical information to support the recommendation given by Contractor as described in Section 2.1, item(s) 23.

Committee and Meetings

4. Provide written meeting notification to P&T members prior to mailing the review packet as defined in a timeline approved by Medicaid for each respective review as described in Section 2.1, item(s) 13.

5. Provide detailed minutes of P&T Committee meetings so that discussion, motions, amendments and recommendations are reflected accurately as described in Section 2.1, item(s) 11.

6. Provide a written P&T Committee update report for the Drug Utilization Review (DUR) Board as described in Section 2.1, item(s) 12. This information may be given in written format to Medicaid Contract Administrator. It should be a brief summary of activity and actions of the P&T Committee. The DUR Board meets a minimum of four times per year.

7. Provide a Medicaid approved professional clinical representative to present oral presentations of clinical reviews at P&T Committee meetings as described in Section 2.1, item(s) 10.

8. Provide notice to manufacturers of upcoming reviews via certified mail return receipt requested; clinical reviews up to the time of the writing of this ITB averaged approximately 100 notices per meeting as described in Section 2.1, item(s) 15.

Preferred Drug Program

9. Provide clinical reviews upon request by Medicaid for coverage, PA determination, override determination, or clinical intervention on drugs or drug classes that fall outside the scope of the PDL and the P&T Committee, not to exceed 2 requested reviews per year as described in Section 2.1, item(s) 29, 31, 34. Potential reviews may include ALGI review on drug file and vitamin/mineral review for coverage.

10. Provide queries to identify AHFS classes and subclasses for review or potential edits. Provide projected cost savings on these groupings based on past claims data, projected utilization shifts, and any other clinical or financial data as described in Section 2.1, item(s) 25, 29, 31, 34.

11. Provide timely notification in writing to Medicaid staff for drugs that are eligible for review or PA as described in Section 2.1, item(s) 25, 34.

12. Provide electronic versions and maintain all PDL lists to include: PDL final posting, PDL by Therapeutic category, PDL by alphabetical order, PDL Reference Tool. PDL documents are updated after each P&T clinical review and on a quarterly basis. Medicaid must approve all drafts and will notify Contractor of deadlines associated with lists as described in Section 2.1, item(s) 24.

13. Provide internal and external criteria as relates to drug classes for review for PDL and on prior authorization as described in Section 2.1, item(s) 28. New or updated criteria must be consistent with current criteria and must be approved by Medicaid. Criteria is developed at the time of the PDL review or edit implementation, final draft is to be approved by Medicaid based on Commissioner approval, and is updated only if needed. Criteria already developed by Medicaid at the time of the writing of this ITB will be updated only if need should arise.

14. Upon implementation of the contract, Contractor shall review and analyze Medicaid's operational policies and procedures related to the Preferred Drug Program as described in Section 2.1, item(s) 27. Within 6 months of the implementation of the contract, Contractor shall provide in writing to Medicaid its analysis and recommendations for changes/improvements.

15. Provide electronic spreadsheets to determine brand versus generic drugs to be reviewed using Medicaid approved methodology as described in Section 2.1, item(s) 30 to include: RedBook data, Orange Book data, and manufacturer data. Notify Medicaid in the event

drugs need to be modified with First DataBank regarding brand versus generic designation.

16. Provide identification of single versus combination products when requested by Medicaid as relates to queries, reviews, projected cost savings, criteria, clinical or financial inquiries as described in Section 2.1, item(s) 3, 25. Make recommendations to Agency when requested regarding single versus combination products.

17. Provide the maximum unit list using methodology approved by Medicaid in electronic format, with all additions/changes identified as described in Section 2.1, item(s) 32. This list should be updated on a biweekly basis according to a timeline approved by Medicaid. New drugs identified for classes already implemented to the max unit list must be approved by or recommended by Medicaid. All additions/changes should be supplied to Medicaid in a separate electronic spreadsheet, in a format approved by Medicaid to include such criteria as drug name, strength, NDC, and GCN so that these updates can be coordinated with First DataBank. Additional drugs classes are added to maximum units list when reviewed for PDL.

18. Upon request by Medicaid, provide recommendations for appropriate coverage or non-coverage of nutritional products using a methodology approved by Medicaid. Contractor will analyze all products to be reviewed and make recommendations to place products on the covered or non-covered list using a methodology approved by Medicaid as described in Section 2.1, item(s) 33. Such requests will not exceed once per quarter.

19. Review weekly the FDB Clinical and Editorial Highlights and provide recommendations of needed action to Medicaid as described in Section 2.1, item(s) 29, 30. Examples include: AHFS classification updates and how these changes may impact our PDL or other edits, gender restrictions implemented by FDB, and GSN additions that may affect max unit restrictions or other edits.

General

20. Provide staff who are available to respond to Medicaid requests in a timely manner. It is expected that all telephone calls, emails and faxes from Medicaid should be responded to within one business day. All requests for information are to be delivered within the timeframe established by Medicaid in coordination with Contractor as described in Section 2.1, item(s) 9.

21. Notify Medicaid in advance if designated Contractor staff will be unavailable or out of the office. A qualified, alternate contact is to be designated as described in Section 2.5.1.

22. Provide designated staff to participate in Medicaid/Contractor meetings/conference calls as scheduled by Medicaid in coordination with Contractor as described in Section 2.1, item(s) 4, 11, 21.

23. Adhere to Medicaid policies for meetings and communications with pharmaceutical industry representatives to include but not limited to those detailed in Attachment G regarding issues contained in the Scope of Work of this ITB.

Hemophilia Audit Program

24. Develop audit procedures for the following (as described in Section 2.1.1, item(s) 1, 2, 3, 4, 13):
    - Each pharmacy providing hemophilia product/service
    - Top 10 Recipient Users (product and cost amount)
    - Recalled Product Analysis
    - Dispensed Dose Assay Analysis
    - Hemophilia Standards of Care Compliance
    - Maintaining client and provider confidentiality during audit process

25. Request pharmacy claims records from participating providers as described in Section 2.1.1, item(s) 5, 6.

26. Draft audit notification and status letter templates to be sent to potentially audited providers as described in Section 2.1.1, item(s) 10.

27. Provide Alabama Medicaid with a listing of pharmacies to be audited as described in Section 2.1.1, item(s) 9.

28. Provide documentation to designated Alabama Medicaid staff of each audit conducted and its outcome as described in Section 2.1.1, item(s) 7, 8.

General

29. Provide staff who are available to respond to Medicaid requests in a timely manner. It is expected that all telephone calls, emails and faxes from Medicaid should be responded to within one (1) business day. All requests for information are to be delivered within the timeframe established by Medicaid in coordination with Contractor as described in Section 2.1.1., item(s) 11, 12.

30. Notify Medicaid, in advance, if designated Contractor staff will be unavailable or out of the office. A qualified, alternate contact is to be designated as described in Section 2.1.1, item(s) 11.

31. Provide designated staff to participate in Medicaid/Contractor meetings/conference calls as scheduled by Medicaid in coordination with Contractor as described in Section 2.1.1, item(s) 13.

32. Adhere to Medicaid policies for meetings and communications with pharmaceutical industry representatives to include but not limited to those detailed in Attachment G regarding issues contained in the Scope of Work of this ITB.

33. Provide a Medicaid approved professional clinical representative to be present at fair hearings as described in Section 2.1.1, item(s) 13.

2.4 Medicaid Responsibilities

1. Provide Contractor with policies for meeting/communication with pharmaceutical industry representatives.

2. Provide instruction to Contractor regarding P&T Committee operational procedures and policies.

3. Schedule Contractor/Medicaid meetings in coordination with Contractor as needed. These meetings may be held via weekly teleconference unless specified in advance by Medicaid.

4. Respond to Contractor requests for information in a timely and professional manner.

5. Provide staff responsible for working with Contractor on assignments and requests.

6. Post the maximum quantity listing on the website.

7. Provide instruction to Contractor regarding requests for research or recommendations as detailed in the Scope of Work.

8. Review and approval of P&T meeting minutes and meeting materials in a timely manner.

9. Post meeting notices, clinical reviews, P&T policies and procedures, recommendations of the P&T Committee, Final PDL documents, PDL listings and P&T member listings to the Medicaid web site.

10. Provide meeting locations for the P&T Committee meeting.

11. Provide Contractor with a final listing of drugs to be included in clinical reviews as described in this ITB.

12. Maintain all administrative authority over the Medicaid Pharmacy Program.

13. Notify Contractor in writing of any concerns regarding Contractor's performance.

2.5 Key Personnel

The contractor must have in place the necessary personnel to perform all duties and responsibilities outlined in this ITB. At a minimum, a Project Manager and a Clinical Pharmacist must be named. It is acceptable for the Project Manager to be the named Clinical Pharmacist.

Medicaid shall have the absolute right to approve or disapprove Contractor's and any subcontractor's staff or to require the removal or reassignment of any personnel found by Medicaid to be unwilling or unable to perform under the terms of the contract. Contractor shall, upon request, provide Medicaid with a resume/CV of any member(s) of its staff or a subcontractor's staff assigned to or proposed to be assigned to any aspect of the performance of this contract. Personnel commitments made on Contractor's response shall not be changed

except as herein above provided or due to the resignation of any named individual. Any personnel of a clinical nature (i.e. pharmacist, physician, nurse, technician, etc.) must have current license and be in good standing with their respective appropriate state board.

2.5.1 Project Manager

Contractor shall assign a Project Manager with a minimum of an Undergraduate Degree to the Alabama Medicaid Agency contract. The Project Manager shall be the person assigned under this contract, who is responsible for operation of contract duties. Contractor shall make a good faith effort to use the same Project Manager throughout the contract. Contractor shall notify Medicaid in writing of any proposed change in Project Manager at least 30 days prior to the change. Contractor shall notify Medicaid immediately of any extenuating circumstances which would prevent Contractor from meeting the 30-day notification time frame. Contractor shall furnish with its response to the ITB a resume for the proposed Project Manager which shall include the individual's name, current address, current title and position, experience with Contractor, experience in performing relevant functions, relevant education and training, and management experience. Two work references shall also be included.

Contractor's Project Manager shall serve as liaison and shall be available and responsible, as the need arises, for consultation and assistance with Medicaid personnel; he/she shall attend, upon request, Medicaid meetings, administrative hearings, meetings and hearings of Legislative Committees and interested governmental bodies, agencies, and officers; and he/she shall provide timely and informed responses when operational and administrative issues arise in administration of the Alabama Medicaid Program. Whenever the Project Manager is not reasonably available, Contractor shall provide a designated alternate fully capable of meeting the requirements of this section.

2.5.2 Clinical Pharmacist

Contractor shall assign a Clinical Pharmacist with a minimum of a Doctor of Pharmacy degree to the Alabama Medicaid Agency contract. This person must have a current license and be in good standing with the appropriate State Board of Pharmacy. The Clinical Pharmacist shall be the person assigned under this contract, who is responsible for the clinical components of the contract duties. He/She must possess superior clinical competence and demonstrate proficiency in drug therapy management. Contractor shall make a good faith effort to use the same Clinical Pharmacist throughout the contract. Contractor shall notify Medicaid in writing of any proposed change in Clinical Pharmacist at least 30 days prior to the change. Contractor shall notify Medicaid immediately of any extenuating circumstances which will prevent Contractor from meeting the 30-day notification time frame. Contractor shall furnish with its response to the ITB a resume for the proposed Clinical Pharmacist which shall include the individual's name, current address, current title and position, experience with Contractor, experience in performing clinical functions, and relevant education and training. Two work references shall also be included.

Contractor's Clinical Pharmacist shall serve as clinical resource and shall be available and responsible, as the need arises, for consultation and assistance with Medicaid personnel; he/she shall attend, upon request, meetings relevant to the scope of work in this ITB to include all meetings of the Pharmacy and Therapeutics Committee. Whenever the Clinical Pharmacist is not reasonably available, Contractor shall provide a designated alternate fully capable of meeting the requirements of this section.

2.5.3 Other Personnel

Contractor shall demonstrate the ability to secure the services of professional staff/expertise to meet contract requirements. This shall include: 1.) staff member with a financial-based education (accounting, statistics, business degree, etc.) for projected cost savings data and 2.) other clinical (to include experts in specific drug class areas of respected review, i.e. mental health drugs, diabetic agents, etc.) and administrative personnel to carry out the requirements of this contract. For example, a previous contractor had an expert in the field of behavioral health medication therapy who was instrumental in developing and presenting the clinical review for those specific AHFS classes. The bid response must clearly outline Contractor's plan to address the personnel requests of this ITB.

Section III General Terms and Conditions

3.1 General

This ITB and Contractor's response thereto shall be incorporated into a contract by the execution of a formal agreement. No alteration or variation of the terms of the contract shall be valid unless made in writing and duly signed by the parties thereto. The contract may be amended by written agreement duly executed by the parties. Every such amendment shall specify the date its provisions shall be effective as agreed to by the parties. The contract and amendments, if any, are subject to approval by the Governor of the State of Alabama and CMS.

3.2 Compliance with State and Federal Regulations

Contractor shall perform all services under the contract in accordance with applicable federal and state statutes and regulations. Medicaid retains full operational and administrative authority and responsibility over the Alabama Medicaid Program in accordance with the requirements of the federal statutes and regulations as the same may be amended from time to time.

3.3 Confidentiality

Contractor shall treat all information, and in particular information relating to enrollees that is obtained by or through its performance under the contract, as confidential information to the extent confidential treatment is provided under State and Federal laws including 45 CFR §160.101 – 164.534. Contractor shall not use any information so obtained in any manner except as necessary for the proper discharge of its obligations and duties under this contract. All information as to personal facts and circumstances concerning enrollees obtained by Contractor shall be treated as privileged communications, shall be held confidential, and shall not be divulged to anyone other than the agencies already specified without written consent of Medicaid or the enrollee, provided that nothing stated herein shall prohibit the disclosure of information in summary, statistical, or other form that does not identify particular individuals. The use or disclosure of information concerning enrollees shall be limited to purposes directly connected with the administration of the State Plan. Upon signing of this contract by all parties, the terms of the contract become available to the public pursuant to Alabama law. Contractor agrees to allow Medicaid or its designee access to all documents, papers, letters, or other material generated under this contract. Contractor will not allow access to such documents to any other person or entity without express consent of Medicaid.

Contractor shall insure safeguards that restrict the use or disclosure of information concerning applicants and recipients to the purpose directly connected with the administration of the Plan in accordance with 42 CFR Part 431, Subpart F, as specified in 42 CFR § 434.6(a)(8). Purposes directly related to the Plan administration include:

(a) Establishing eligibility;
(b) Determining the amount of medical assistance;
(c) Providing services for recipients; and
(d) Conducting or assisting an investigation, prosecution, or civil or criminal preceding related to the administration of the Plan.

Pursuant to requirements of the Health Insurance Portability and Accountability Act (HIPAA) of 1996 (Public Law 104-191), the successful contractor will be required to sign a Business Associate agreement with the Agency.

3.4 Term of Contract

It is understood and agreed by the parties that every effort will be made to ensure the successful completion of this contract. The initial contract shall be for 12 months commencing July 1, 2008, through June 30, 2009. Medicaid shall have three (3) one year options for extending this contract. At the end of each contract year Medicaid may at its discretion, exercise the extension option and allow the period of performance to be extended for an additional contract year. The payment rate during the period prior to execution of the succeeding contract extension year shall be the same as the rate paid during the preceding contract year. In no event shall the term of the original contract plus the three extension year options exceed a total of four contract years.

The contract shall include the following:

1. Executed contract,
2. ITB, and any amendments thereto,
3. Contractor's response to the ITB, and shall be construed in accordance with and in the order of the applicable provisions of:
    - Title XIX of the Social Security Act, as amended and regulations promulgated thereunder by HHS and any other applicable federal statutes and regulations
    - The statutory and case law of the State of Alabama
    - The Alabama State Plan for Medical Assistance under Title XIX of the Social Security Act, as amended
    - The Alabama Medicaid Agency Administrative Code
    - Medicaid's written response to prospective bidder's questions

3.5 Contract Amendments

The contract shall be deemed to include all applicable provisions of the State Plan and of all state and federal laws and regulations applicable to the Alabama Medicaid Program, as they may be amended. In the event of any substantial change in such Plan, laws, or regulations, that materially affects the operation of the Alabama Medicaid Program or the costs of administering such Program, either party, after written notice and before performance of any related work, may apply in writing to the other for an equitable adjustment in compensation caused by such substantial change. In the event of any such substantial change that decreases Contractor's cost of performance, Medicaid shall be entitled to a decrease in Contractor reimbursement commensurate with such substantiated change. In the event of any substantial change mandated by Medicaid that increases Contractor's cost of performance, Contractor may, in the sole discretion of Medicaid, be entitled to an increase in reimbursement commensurate with such substantiated increased cost.

3.6 Termination for Bankruptcy

The filing of a petition for voluntary or involuntary bankruptcy or a company or corporate reorganization pursuant to the Bankruptcy Act shall, at the option of Medicaid, constitute default by Contractor effective the date of such filing. Contractor shall inform Medicaid of any such action(s) immediately upon occurrence by the most expeditious means possible.

3.7 Termination for Default

Medicaid may, by written notice, terminate performance under the contract, in whole or in part, for failure of Contractor to perform any of the contract provisions. In the event, Contractor defaults in the performance of any of Contractor's material duties and obligations, written notice shall be given to Contractor specifying default. A copy of the written notice shall be sent to the Surety for Contractor's Performance Bond. Contractor shall have 10 calendar days, or such additional time as agreed to in writing by Medicaid, after the mailing of such notice to cure any default. In the event Contractor does not cure a default within 10 calendar days, or such additional time allowed by Medicaid, Medicaid may, at its option, notify Contractor in writing that performance under the contract is terminated and proceed to seek appropriate relief from Contractor and Surety.

3.8 Termination Without Cause

Medicaid may, at its option, terminate performance under the contract, without cause in whole or part. In the event of said termination, Medicaid shall notify Contractor in writing a minimum of thirty (30) days in advance of contract end date.

3.9 Termination for Unavailability of Funds

Performance by the State of Alabama of any of its obligations under the contract is subject to and contingent upon the availability of state and federal monies lawfully applicable for such purposes. If Medicaid, in its sole discretion, deems at any time during the term of the contract that monies lawfully applicable to this agreement shall not be available for the remainder of the term, Medicaid shall promptly notify Contractor to that effect, whereupon the obligations of the parties hereto shall end as of the date of the receipt of such notice and the contract shall at such time be cancelled without penalty to Medicaid, State or Federal Government.

3.10 Force Majeure

Contractor shall be excused from performance hereunder for any period Contractor is prevented from performing any services pursuant hereto in whole or in part as a result of an act of God, war, civil disturbance, epidemic, or court order; such nonperformance shall not be a ground for termination for default.

3.11 Transfer of Documents

At Medicaid's discretion, but no later than three working days following expiration or termination of the contract, Contractor, at its expense, shall box, label, and deliver to Medicaid, any information, data, manuals, or other documentation collected hereto and which shall permit Medicaid to continue contract performance or contract for further performance by others.

3.12 Nondiscriminatory Compliance

Contractor shall comply with Title VII of the Civil Rights Act of 1964, Section 504 of the Rehabilitation Act of 1973, the Age Discrimination Act of 1975, Executive Order No. 11246, as amended by Executive Order No. 11375, both issued by the President of the United States, the Americans with Disabilities Act of 1990, and with all applicable federal and state laws, rules and regulations implementing the foregoing statutes with respect to nondiscrimination in employment.

3.13 Small and Minority Business Enterprise Utilization

In accordance with the provisions of 45 CFR Part 74, paragraph 9 of OMB Circular A-102, affirmative steps shall be taken to assure that small and minority businesses are utilized when possible as sources of supplies, equipment, construction, and services.

3.14 Worker's Compensation

Contractor shall take out and maintain, during the life of this contract, Worker's Compensation Insurance for all of its employees under the contract or any subcontract thereof, if required by state law.

3.15 Employment of State Staff

Contractor shall not knowingly engage on a full-time, part-time, or other basis during the period of the contract any professional or technical personnel, who are or have been in the employment of Medicaid during the previous 12 months, except retired employees or contractual consultants, without the written consent of Medicaid.

3.16 Security and Release of Information

Contractor shall take all reasonable precautions to ensure the safety and security of all information, data, procedures, methods, and funds involved in the performance under the contract, and shall require the same from all employees so involved. In compliance with 42 CFR §431.300 et seq. Contractor shall conform to the requirements of federal and state regulations regarding confidentiality of information about eligible recipients. Contractor shall not release any data or other information relating to the Alabama Medicaid Program without prior written consent of Medicaid. This provision covers both general summary data as well as detailed, specific data. Contractor shall not be entitled to use of Alabama Medicaid Program data in its other business dealings without prior written consent of Medicaid. All requests for program data shall be referred to Medicaid for response by the Commissioner only.

3.17 Share of Contract

No official or employee of the State of Alabama shall be admitted to any share of the contract or to any benefit that may arise therefrom.

3.18 Conflict of Interest

A conflict of interest exists where the Contractor will receive direct or indirect financial gain as a result of prior authorization, maximum quantity restrictions or the inclusion or exclusion of a drug on the Medicaid Preferred Drug List. A conflict of interest also exists where the Contractor has a contract, business arrangement or other professional association with, or acts as the personal or professional representative of a physician, pharmacist, or other Medicaid provider affected by the decision made on the above listed issues. Medicaid reserves the right to determine in its sole discretion what constitutes a conflict of interest.

3.19 Performance Bond

Contractor shall post a performance bond with a corporate bonding company licensed by the Alabama Department of Insurance as surety upon execution of the contract to be effective no later than the first day of the first month in which payments are made in accordance with the provisions of Code of Alabama, 1975, Section 41-16-28. The performance bond shall be in the

amount equal to two monthly payments. This bond shall be in force from that date through the term of the contract and 180 calendar days beyond and shall be conditioned on faithful performance of all contractual obligations. Failure of Contractor to perform satisfactorily, breach of contract, or termination of the contract shall cause the performance bond to become due and payable to the State of Alabama to the extent necessary to cover the cost incurred by Medicaid as a result of Contractor's failure to perform its contractual obligations. These costs include, but are not limited to, costs to correct any Medicaid program errors caused by Contractor's default and costs incurred by Medicaid for completion of the contracted work, including any costs associated with the preparation, solicitation, and award of a competitive bid for these contract services and any federal state or other penalties, sanctions, disallowances, or other such costs incurred by Medicaid as a result of Contractor's default and legal, administrative, and delay costs incurred as a result of Contractor's default and any liquidated damages necessary as a result of Contractor's default. The Commissioner of Medicaid shall be custodian of the performance bond. Said bond shall be extended in the event Medicaid exercises its option to extend the contract.

3.20 Indemnification

Contractor shall hold harmless, defend and indemnify Medicaid as to any penalties or federal recoupment and any interest incurred by reason of any Title XIX noncompliance due to the fault of Contractor and/or any subcontractors. The term "Title XIX noncompliance" shall be construed to mean any failure or inability of Medicaid to meet the requirements of Title XIX of the Social Security Act, due to an act or omission of Contractor or subcontractor and/or any regulations promulgated by the federal government in connection therewith.

Contractor shall be liable and agrees to be liable for and shall indemnify, defend, and hold the State and Medicaid and their officers, employees and agent harmless from all claims, suits, judgments or damages, including court costs and attorney fees, arising out of or in connection with this contract due to negligent or intentional acts of omissions of the Contractor and/or any subcontractors. Contractor shall hold the State and Medicaid harmless from all subcontractor liabilities under the terms of this contract.

Contractor agrees to indemnify, defend, and hold harmless Medicaid, its officers, agents, and employees from:

1. Any claims or losses attributable to a service rendered by Contractor or any subcontractor, person, or firm performing or supplying services, materials, or supplies in connection with the performance of the contract regardless of whether Medicaid knew or should have known of such improper service, performance, materials or supplies unless otherwise specifically approved by Medicaid in writing in advance.

2. Any claims or losses attributable to any person or firm injured or damaged by the erroneous or negligent acts, including without limitation, disregard of Federal or State Medicaid regulations or statutes, of Contractor, its officers, employees, or subcontractors in the performance of the contract, regardless of whether Medicaid knew or should have known of such erroneous or negligent acts.

3. Any failure of Contractor, its officers, employees, or subcontractors to observe Alabama laws, including, but not limited to, labor laws and minimum wage laws, regardless of whether

Medicaid knew or should have known of such failure.

4. If at any time during the operation of this contract, Medicaid gains actual knowledge of any erroneous, negligent, or otherwise wrongful acts by Contractor, its Officers, employees, or subcontractors, Medicaid agrees to give Contractor written notice thereof. Failure by Medicaid to give said notice does not operate as a waiver of Contractor's obligations to Medicaid, or a release of any claims Medicaid may have against Contractor.

3.21 Waivers

No covenant, condition, duty, obligation, or undertaking contained in or made a part of the contract shall be waived except by written agreement of the parties.

3.22 Warranties Against Broker's Fees

Contractor warrants that no person or selling agency has been employed or retained to solicit or secure the contract upon an agreement or understanding for a commission percentage, brokerage, or contingent fee excepting bona fide employees. For breach of this warranty, Medicaid shall have the right to terminate the contract without liability.

3.23 Novation

In the event of a change in the corporate or company ownership of Contractor, Medicaid shall retain the right to continue the contract with the new owner or terminate the contract. The new corporate or company entity must agree to the terms of the original contract and any amendments thereto. During the interim between legal recognition of the new entity and Medicaid execution of the novation agreement, a valid contract shall continue to exist between Medicaid and the original Contractor. When, to Medicaid's satisfaction, sufficient evidence has been presented of the new owner's ability to perform under the terms of the contract, Medicaid may approve the new owner and a novation agreement will be executed.

3.24 Employment Basis

It is expressly understood and agreed that Medicaid enters into this agreement with Contractor and any subcontractor as authorized under the provisions of this contract as an independent contractor on a purchase or service basis and not on an employer-employee basis and not subject to State Merit System law.

3.25 Disputes and Litigation

Except in those cases where the bid response exceeds the requirements of the ITB, any conflict between the bid response of Contractor and the ITB shall be controlled by the provisions of the ITB. Any dispute concerning a question of fact arising under the contract which is not disposed of by agreement shall be decided by the Commissioner of Medicaid.

Any litigation brought by Medicaid or Contractor to enforce any provision of the contract shall be brought in either the Circuit Court of Montgomery County, Alabama, or the United States District Court for the Middle District of Alabama, Northern Division, according to the jurisdictions of these courts. This provision shall not be deemed an attempt to confer any jurisdiction on these courts which they do not by law have, but is a stipulation and agreement as to forum and venue only.

3.26 Records Retention and Storage

In accordance with 45 CFR §74.164, Contractor shall maintain financial records, supporting documents, statistical records, and all other records pertinent to the Alabama Medicaid Program for a period of three years from the date of the final payment made by Medicaid to Contractor under the contract. However, if audit, litigation, or other legal action by or on behalf of the State or Federal Government has begun but is not completed at the end of the three year period, or if audit findings, litigation, or other legal action have not been resolved at the end of the three year period, the records shall be retained until resolution. Subsequent to the contract term, documents shall be returned to Medicaid within three working days following expiration or termination of the contract. Micromedia copies of source documents for storage may be used in lieu of paper source documents subject to Medicaid approval.

3.27 Inspection of Records

Contractor agrees that representatives of the Comptroller General, HHS, the General Accounting Office, the Alabama Department of Examiners of Public Accounts, and Medicaid and their authorized representative shall have the right during business hours to inspect and copy Contractor's books and records pertaining to contract performance and costs thereof. Contractor shall cooperate fully with requests from any of the agencies listed above and shall furnish free of charge copies of all requested records. Contractor may require that a receipt be given for any original record removed from Contractor's premises.

3.28 Use of Federal Cost Principles

For any terms of the contract which allow reimbursement for the cost of procuring goods, materials, supplies, equipment, or services, such procurement shall be made on a competitive basis (including the use of competitive bidding procedures) where practicable, and reimbursement for such cost under the contract shall be in accordance with 48 CFR, Chapter 1, Part 31. Further, if such reimbursement is to be made with funds derived wholly or partially from federal sources, such reimbursement shall be subject to Contractor's compliance with applicable federal procurement requirements, and the determination of costs shall be governed by federal cost principles.

3.29 Invoice Submission

Contractor shall submit to Medicaid monthly a detailed invoice for compensation for the previous month's services. Any subsequent charges through contract amendments should be detailed individually.

3.30 Payment

Alabama Medicaid will make payments for successful completion of deliverables/requirements received and accepted as specified in the Scope of Work and any contract amendments. Payments are dependent upon successful completion and acceptance of described work and delivery of required documentation.

3.31 Notice to Parties

Any notice to Medicaid under the contract shall be sufficient when mailed to the Alabama Medicaid Agency, Attention Louise Jones, Pharmacy Services, 501 Dexter Avenue, P.O. Box 5624, Montgomery, Alabama 36103-5624. Any notice to Contractor shall be sufficient when mailed to Contractor at the address given on the return receipt from this ITB or on the contract after signing. Notice shall be given by certified mail, return receipt requested.

3.32 Cooperation

Effective operation of the Alabama Medicaid Program shall require close cooperation between Medicaid and Contractor. To this end, the parties agree to work mutually in solving operational problems. Contractor shall make known and fully describe to Medicaid, in writing, any difficulties encountered that threaten required performance or when such a potential exists. Such difficulties may include, but not be limited to, scheduling problems, meeting reporting requirements, accuracy of data, etc. If Contractor determines that Medicaid's input or direction is required to resolve the difficulties, such an explanation describing the desired input along with any applicable timetables and projected corrections shall be included in a report. Contractor shall notify the Medicaid Contract Administrator by telephone within one working day of discovery of any problem which has already occurred, or within one working day of the identification of potential problems that threaten required performance. All telephone notices shall be followed up in writing, including any action taken.

3.33 Liquidated Damages

Contractor shall be liable for any penalties and late deliverables or disallowance of Federal Financial Participation incurred by Medicaid due to Contractor's failure to comply with the terms of the contract. Imposition of liquidated damages may be in addition to other contract remedies, and does not waive Medicaid's right to terminate the contract.

The following liquidated damages shall be accessed against contractor for:

1. Failure to produce required report or any contractor deliverable as referenced in Section 2.3- $100 per day per report/deliverable
2. Failure to safeguard confidential information of providers, recipients or the Medicaid program as referenced in Section 2.1-$2,500 per instance plus any penalties incurred by Medicaid for said infractions
3. Failure to meet technical or personnel requirements as referenced in Section 2.5-$100 per day that requirement is not met
4. Failure to develop, obtain Medicaid approval and mail reviews for P&T Committee meetings in accordance with required timeline as referenced in Section 2.3 -$500 per day
5. Failure to produce minutes of P&T Committee meetings to Medicaid for approval within fourteen calendar days following the meeting as referenced in Section 2.3-$100 per day
6. Failure to produce minutes of P&T Committee meetings to Medicaid for final sign-off within 5 business days after receiving approval from Medicaid as referenced in Section 2.3-$100 per day
7. Use of materials without prior review or approval by Medicaid as referenced in Section 2.1-$2,500 per instance
8. Failure to include Medicaid requested changes/corrections/revisions in deliverables as referenced in Section 2.3-$100 per change/correction/revision per document

9. Failure of designated Contractor staff to be punctual for P&T Committee meetings as referenced in Section 2.1-$250 per minute past scheduled start time
10. Presentations to groups/associations or others regarding this contract and work there under without prior approval of Medicaid as referenced in Section 2.3-$2,500 per instance
11. Failure to comply with meeting and communication policy involving the pharmaceutical industry as provided by Medicaid as referenced in Section 2.3-$2,500 per instance
12. Failure to produce PDL lists as referenced in Section 2.3-$100 per day
13. Failure to develop and obtain Medicaid approval for reviews requested as referenced in Section 2.3-$500 per day
14. Failure to notify manufacturers for upcoming meetings as referenced in Section 2.3-$250 per day per manufacturer not notified
15. Failure to develop, maintain, and obtain Medicaid approval for internal/external criteria as referenced in Section 2.1-$500 per day per class or subclass per criteria
16. Failure to provide projected cost savings and drug lists by AHFS classes, as requested by Medicaid as referenced in Section 2.1-$100 per day per request
17. Failure to determine and identify brand versus generic drugs or OTC versus legend drugs as requested by Medicaid as referenced in Section 2.3-$100 per day per request
18. Failure to respond to clinical appeal as referenced in Section 2.3-$100 per day per appeal
19. Failure to provide maximum unit list as referenced in Section 2.1- $100 per day per routine timeline

Section IV Bid Procedures

4.1 General Response Requirements

Each bid shall be submitted with one original and five hard copies under sealed cover, along with one electronic copy (CD using MS Word 6.0 or higher format), and shall be received in accordance with the schedule of activities Section 1.8. Sealed bid packages shall be delivered or sent by mail to:

State of Alabama
Division of Purchasing
RSA Union Building
100 N. Union Street
Suite 192
Montgomery, AL 36130-2401

Attention: Bernie Arant

The outside cover of the package containing the response shall be marked:

Alabama Medicaid Pharmacy Clinical Support
BID # 08-X-2192281
Opening Date: 5/19/08

Bids submitted in whole or part by modem or fax will be rejected. Late responses will not be accepted. It is the responsibility of the bidder to ensure the bid is delivered by the time specified. Bids received after that time will not be considered. Bidders must submit the following documents to the Division of Purchasing:

4.2 Transmittal Letter

The Transmittal Letter shall include:

a. Identification of all materials and enclosures being submitted collectively as a response to this ITB.

b. A statement identifying each addendum to this ITB that has been received; if no addenda have been received, a statement to that effect shall be included. The bidder shall list each ITB addendum acknowledged and received by addendum number.

c. Identification of the bidder that will be the prime contractor and the name of the corporation or other legal entity submitting the proposal. It shall also include a statement identifying any and all subcontractors that are needed in order to satisfy the requirements of this ITB. The percentage of work, as measured by percentage of total contract price, to be performed by the prime contractor shall be provided. The bidder will assume sole and exclusive responsibility for all of the contractor responsibilities and work indicated in the ITB (including any and all addenda).

d. A statement certifying that, if a foreign corporation, the bidder has a current Certificate of Authority to do business in Alabama issued from the Alabama Secretary of State.

e. A statement of compliance with Affirmative Action and Equal Employment Opportunity regulations that confirms that the bidder does not discriminate in its employment practices with regard to race, color, religion, age (except as provided by law), sex, marital status, developmental disability, political affiliation, national origin, or handicap, and complies with all applicable provisions of Public Law 101-336, Americans with Disabilities Act.

f. A statement acknowledging and agreeing to all of the rights of the Alabama Medicaid Agency contained in the provisions of this ITB.

g. A statement that the prices proposed have been arrived at independently without consultation, communication, or agreement with any other bidder or competitor for this procurement.

h. A statement that the bidder, through its duly authorized representatives, has in no way entered into any arrangement or agreement with any other bidder or competitor which could lessen or destroy free competition in awarding the contract sought by the attached proposal.

i. A statement that, unless otherwise required by law, the prices quoted shall not be knowingly disclosed by the bidder, directly or indirectly, prior to award of the contract, to any other bidder or to any competitor.

j. A statement that the bidder has not and will not make any attempt to induce any other person or firm to withhold or submit a proposal for the purposes of restricting competition.

k. A statement that the person signing this bid is authorized to make decisions on behalf of the bidder's organization as to the prices quoted.

l. A statement that the bidder has not employed anyone, other than a bona fide employee working solely for the bidder, in soliciting or securing this contract.

m. A statement that no person or agency has been employed or retained to solicit or secure the proposed contract based on an agreement or understanding for a commission, percentage, brokerage, or contingent fee.

n. A statement that the bidder, and any subcontractors, will maintain a drug-free workplace.

If the use of subcontractors is proposed, a statement from each subcontractor, on official letterhead, shall be attached to the Transmittal Letter, signed by an individual authorized to legally bind the subcontractor to perform the scope of work as assigned, stating:

a. The general scope of work to be performed by the subcontractor

b. The subcontractor's willingness to perform the work indicated

c. The names and titles of individuals who will be responsible for the subcontractor's efforts

d. That the subcontractor's firm does not discriminate in its employment practices with regard to race, color, religion, age (except as provided by law), sex, marital status, developmental disability, political affiliation, national origin, or handicap, and complies with all applicable provisions of Public Law 101-336, Americans With Disabilities Act

If the bidders' response deviates, in any way whatsoever, from the detailed specifications and requirements in the ITB, the Transmittal Letter shall explicitly identify and explain these deviations. The Alabama Medicaid Agency reserves the right, at its sole discretion, to reject any proposal containing such deviations or to require modifications and/or clarifications before acceptance.

Bidders may not place any conditions, reservations, limitations, or substitutions in their response with regard to the contract terms and conditions. The bidder selected under this ITB may request non-substantive changes to the contract language, but the State reserves the sole right to accept or reject any requested changes.

4.3 Bid Response

The bid response must present a complete and detailed description of the bidder's qualifications to perform, and its approach to carry out the requirements in Section II, Scope of Work, of this ITB. Any deviations in the bidder's response from the outline described below could disqualify that bid due to evaluation considerations. The name and number of this ITB shall be included on the title page of each volume.

The response shall include ten separate sections (with named and numbered tabs) presented in the following order:

1. Transmittal Letter
2. Table of Contents and ITB Cross-Reference
3. Executive Summary
4. Work plan for various required components
5. Approach to Administrative Responsibilities
6. Corporate Capabilities and Commitment
7. Bidder's Understanding of Alabama Requirements
8. Two references, at a minimum for both Contractor and Key Personnel
9. Submission of firm and fixed bid price
10. Appendices

Each response (including all copies thereof) shall be 1) clearly page-numbered on the bottom (center or right) of each page, 2) submitted in three-ring binders, and 3) use 8.5 x 11-inch paper and two-sided copies. A type size of 11 points or larger shall be used.
Brochures or other presentations, beyond that sufficient to present a complete and effective response, are not desired. Audio and/or videotapes are not allowed. Elaborate artwork or expensive paper is not necessary or desired.

The Division of Purchasing desires and encourages that bids be submitted on recycled paper, printed on both sides. While the appearance of proposals and professional presentation is important, the use of non-recyclable or non-recycled glossy paper is discouraged.

4.4 Firm and Fixed Bid Price
The bid response will include the bidder's total Fixed Bid Price representing the fixed, not estimated, costs that bidder requires in order to complete this project according to the requirements of the ITB. Estimated total Fixed Bid Price cost responses cannot be evaluated and will not be considered. Payments will be based upon contracted services actually performed in accordance with the submitted Fixed Price.

4.5 Bid Guarantee
Each sealed response shall be accompanied by a bid guarantee consisting of a bid bond issued by a company authorized to do business in the State of Alabama. The guarantee shall be payable to the State of Alabama in the amount of $5,000, as a guarantee of good faith and to ensure a firm bid for contracting purposes for 90 calendar days after bid due date. Bid guarantees provided by unsuccessful bidders shall be returned after 90 calendar days.

4.6 Bid Opening
Bid responses shall be opened in accordance with the Schedule of Activities at the office of the State Department of Finance, Division of Purchasing, Suite 192, RSA Union Building, 100 N. Union Street, Montgomery, Alabama. This process is open to the public.

4.7 Acceptable Bid Responses
All bids become the property of the State of Alabama, and none shall be returned to the bidder. Only bids that conform to the requirements of this solicitation shall be acceptable. The state reserves the right to reject any or all bids. There is no guarantee that a contract shall result from this solicitation. The State accepts no obligation for costs incurred by any bidder in the preparation of a bid in response to this ITB.

4.8 Protest Guarantee
Any protest filed after the award of the bids shall be accompanied by a bond issued by a company authorized to do business in the State of Alabama. The guarantee shall be payable to the State of Alabama and shall be in an amount that will be an adequate guarantee of good faith in the filing of such protest and in an amount that will allow the Alabama Medicaid Agency to recover the costs incurred as a result of the filing of an unsuccessful bid protest. This bond will be returned to the protester shall such protest be well founded. The amount of the bond shall be $10,000.

4.9 Evaluation of Bids

The State of Alabama will conduct a comprehensive, fair, and impartial evaluation of bids received in response to the ITB. Initially only the bid with the low price will be evaluated to determine whether mandatory requirements are met. If it is found to be non-responsive then the next lowest bid will be considered. This process will be followed until such time a bid is found to be responsive. Medicaid reserves the right to reject any or all bids.

4.10 Evaluation Participants

A Selection Committee composed of the Alabama Medicaid Agency management and staff will be responsible for reviewing the bids for responsiveness to the bid requirements.

4.11 Evaluation Of Mandatory Requirements

The purpose of this phase is to determine whether the low price bid has met the response submission requirements, and conforms with the rules of the procurement. Bids will be evaluated on a pass/fail basis for each requirement.

Any response that fails to comply with response submission instructions or meet the mandatory requirements listed in this ITB will be deemed "non-responsive" and the bid will be rejected by the Selection Committee. The State reserves the right to reject any and all bids.

4.12 Contract Award

The low price bid that has met the response submission requirements and passes the mandatory requirements will be considered for contract award. The successful bidder will be notified in writing of award of contract.

Section V Attachments

5.0 Attachments

Attachments to this ITB are outlined below:

A. Example of Formal Agreement
B. Definitions
C. Mandatory Bid Requirements Checklist
D. Medicaid PDL List
E. Medicaid PDL Operating Procedures
F. Clinical Review Reference Sheet
G. Policy for Meeting with Pharmaceutical Industry Representatives
H. Maximum Unit List and Nutritional List Reference Sheet
I. Hemophilia Management Standards of Care

Attachment A

Example of Formal Agreement

State of Alabama
Montgomery County

KNOW ALL MEN BY THESE PRESENTS, that the Alabama Medicaid Agency, an Agency of the State of Alabama, and the undersigned Contractor agree as follows:

1. Contractor shall furnish all labor, equipment, and materials and perform all of the work required under the Invitation to Bid, No. 08-X-2192281, dated April 2, 2008, strictly in accordance with the requirements thereof and Contractor's bid response thereto.

2. Contractor shall be compensated for performance under this contract at the rate of $_____ per month.

3. This contract specifically incorporates by reference the said Invitation to Bid, any amendments thereto, and Contractor's bid response, including all attachments.

EXECUTED this _____ day of _____, 2008.

ALABAMA MEDICAID AGENCY
An Agency of the State of Alabama

WITNESS:

_____
Alabama Medicaid Agency

By: _____
Commissioner
Alabama Medicaid Agency

APPROVED AS TO FORM:

_____
Attorney, Alabama Medicaid Agency

_____
Contractor

WITNESS:

_____
Contractor

By: _____
Title

Contractor's Address:
_____
_____
_____

APPROVED: _____
Governor, State of Alabama

Definitions

Administrative Hearing: a formal face-to-face hearing by an impartial State Hearing Officer attended by the complainant or an authorized representative(s).

Administrative Review: a thorough review by Medicaid allowing providers an opportunity to submit additional written documentation.

Adverse Reaction: the development of undesired side effects or toxicity caused by prescription drugs.

AHFS (American Hospital Formulary Services): An unbiased source of comprehensive and evaluative drug data available for healthcare professionals. Alabama Medicaid is mandated at the time of the writing of this ITB to conduct its PDL clinical reviews based on AHFS classification.

Alabama Medicaid Agency: the single State Agency designated to administer the medical program under Title XIX of the Social Security Act.

Alabama Medicaid Agency Administrative Code: publication containing information about the administration of the Medicaid program and the extent of the covered services available for eligible categorically needy recipients when medically prescribed.

ALGI (Alabama Generic Indicator): An Alabama specific brand/generic indicator that describes if a drug is brand or generic according to methodology defined by Medicaid. This methodology includes utilizing RedBook, FDA Orange Book, and manufacturer data.

AMMIS: the Alabama Medicaid Management Information System that consists of all subsystems of the AMMIS maintained by Medicaid's fiscal agent.

Brand Drug: Those drug products that are not considered therapeutically equivalent by the FDA. These products are deemed "innovator", "Reference Listed Drug", and/or have an appropriate FDA application number listed in Orange Book, or are indicated as brand products in RedBook or the drug manufacturer.

Case Management: the coordination of the total spectrum of medical care, involves planning, coordination, implementation, monitoring and evaluation of care and the effectiveness of that care towards meeting the specific needs of an individual patient.

Designated Pharmacy Staff: as relates to this ITB, pharmacy staff that are expected to coordinate with the clinical Contractor on any related issue. Designated Pharmacy Staff includes PDL Administrator, Medicaid Clinical Pharmacist, and Director of Pharmacy Services.

Dispensing Pharmacist: state licensed pharmacist, enrolled in the Alabama Medicaid Agency, authorized to dispense prescription medication to Medicaid recipients.

Drug Class: those drugs with the same therapeutic classification.

Drug Sub-class: those drugs within the same therapeutic classification, more specific than drug class.

Drug Usage Review Criteria: predetermined standards of indications for medical necessity for certain drug classes which are compared to medical documentation submitted by physicians.

Drug Utilization Review (DUR): a structured and continuing program that reviews, analyzes and interprets patterns of drug usage in a given health care environment against predetermined criteria and standards.

DUR Board: advisory board regarding matters of drug utilization review. The group consists of Medicaid enrolled practicing physicians and dispensing pharmacists and meets a minimum of four times per year to advise Medicaid on drug utilization issues.

Duplicate Request: a PA Request which contains identical or similar information submitted in a previous request which was approved or denied within the past thirty (30) days.

Enterals: Nutritional products which may be administered orally or via nasogastric tube, feeding gastrostomy, or needle-catheter jejunostomy.

FDB: First DataBank

FDB Notification: written or electronic updates to the drug file sent by First DataBank. These updates can either be on a weekly or biweekly basis.

Fiscal Agent: a Contractor that processes or pays provider claims on behalf of Medicaid.

GSN (Generic Code Number): A five digit code number that represents a generic formulation specific to generic ingredients, drug strength, dosage form and route of administration.

HHS: Department of Health and Human Services is a cabinet level department which administers all federal health care services, including Medicare, Medicaid, and federal employees insurance.

Legend Drug: those drugs requiring a prescription in accordance with FDA guidelines

Lock-in: a recipient who has failed to comply with Medicaid program requirements may be restricted, or "locked-in," to a specified physician and pharmacy. The recipient's eligibility record will indicate when the recipient is restricted.

MAC Program: State Maximum Allowable Cost Program

Maximum Unit List: (Also known as the Max Unit List or Maximum Unit Requirements) A list of drugs that require override if prescribed in greater quantities than allowed. Medicaid methodology utilizes FDA guidelines when determining max unit limitations.

Medical Necessity: the need or condition documented on submitted information compared to established criteria which indicates appropriateness of the use of prescription drugs necessary to treat certain medical conditions.

Multiple Source Brand Name: drugs marketed or sold by two or more drug manufacturers or sold by the same manufacturer or labeler under two or more different proprietary names or both under a proprietary name and without such a name.

NDC (National Drug Code) : a nationally recognized 11-digit number used to identify a drug. The first five digits identify the company that manufacturers the drug, the next four digits identify the drug and its strength, and the last two digits indicate the package size.

Nonsteroidal Anti-Inflammatory Drugs (NSAIDs) : drugs which have analgesic and antipyrectic activities. Most NSAIDs are primarily used for their anti-inflammatory effects and are effective analgesics useful for relief of mild to moderate pain. These agents do not alter the course of the underlying disease.

Nutritional Product List: A list of nutritional drugs, usually OTC in nature, that may be administered orally or via nasogastric, jejunostomy, or gastrostomy tubes. Medicaid posts List A (non-covered agents) and List C (covered agents) to our website, and maintains a List B (agents to be reviewed) until the clinical determination has been made to move agents from List B to either List A or C.

OTC Drug: those drugs deemed over the counter by the FDA.

Override Program: Edits that require review and determination of the medical necessity and appropriateness of drugs and drug classes prescribed for the treatment of medical conditions prior to the reimbursement from Medicaid. Overrides that are included in the Override Program at the time of the writing of this ITB include Therapeutic Duplication, Maximum Unit, Brand Limit Switchover, and Early Refill.

PA List: list of drugs that require authorization prior to payment

PA Request, Approved: a request meeting the review criteria for Medicaid coverage and assigned a PA number.

PA Request, Denied: a request not meeting the review criteria for Medicaid coverage.

Pass Through Expense (also referred to as Extra-contractual services): Those expenses of Contractor which are to be reimburse at cost by Medicaid. Includes reimbursement only for costs incurred as a result of additional requirements by Medicaid which increase the volume or scope of work to be performed by Contractor above the ITB requirements.

Pharmacy and Therapeutics (P&T) Committee: Expert panel of Medicaid enrolled physicians and pharmacists with well developed medical and pharmacological backgrounds that review drugs for preferred drug status, review drugs for prior authorizations and make program recommendations to Medicaid.

Physician: a doctor of medicine, osteopathy, or dentistry or another individual who is authorized under State or Federal law to practice medicine and surgery or osteopathy.

Preferred Drug List: List of drugs recognized by the P&T Committee as superior drugs within their class that are recommended for usage to the Medicaid provider community.

Prior Authorization (PA): a review and determination of the medical necessity and appropriateness of certain drug classes prescribed for treatment of medical conditions prior to reimbursement from Medicaid.

Professional Staff: licensed clinical staff, i.e.: pharmacist, physician, nurse or technician pharmacist(s) and physician(s) employed by Contractor to review PA Request(s) for Medicaid coverage.

Prospective DUR: On-line drug screening system that alerts pharmacists to certain drug concerns such as early refill, therapeutic duplication, drug/drug interactions and high dose.

Provider: a physician or pharmacy that is enrolled by Medicaid to provide services.

QMB (Qualified Medicare Beneficiary): part A Medicare beneficiary whose verified income and resources do not exceed certain levels.

QMB Only: category of recipients eligible only for services included in Medicare coverage. Coverage for prescription drugs is not a benefit for this category.

Recipient: a person who has been certified as eligible for medical assistance under the State Plan and has been assigned a Medicaid identification number.

Retroactive Eligibility: category of recipients that have been determined to have been eligible three months prior to application for Medicaid eligibility.

SLIMB (Specified Low Income Medicare Beneficiaries): patients for which Medicaid pays Part B premiums only; these patients are not eligible for drug benefits through Medicaid.

State Plan: the State Plan for Medical Assistance of the State of Alabama, as amended, is a comprehensive written commitment for administration of the Medicaid program approved by HHS for federal financial participation under Title XIX of the Social Security Act.

State Supplemental Rebate: A rebate per unit offered by a pharmaceutical manufacturer in addition to the mandated CMS rebate.

Therapeutic Classification Code: a six- or eight-digit number arrangement which groups drugs with similar activities. This numbering scheme is copyrighted as the American Hospital Formulary Services Pharmacologic-Therapeutic Classification.

Title XIX: that part of the Social Security Act which established the Medicaid program.

Attachment C

Mandatory Bid Requirements Checklist

1. Has company had business license for minimum of three years?
2. Is company licensed to do business in Alabama?
3. Did bidder submit original and five copies of bid and an electronic copy on CD?
4. Were all requirements specified by the ITB provided?
5. Does the bid cover the time period specified?
6. Does the bid accept the requirement for a performance bond?
7. Is the bid accompanied by a bid guarantee for five thousand dollars ($5,000)?
8. Does the price sheet state a firm and fixed price?
9. Is page 1 of ITB signed and notarized?
10. Was overview of company history and structure provided, as well as a description of the organization's overall capabilities?
11. Does the bid demonstrate the ability to secure and retain professional staff to meet contract requirements to include clinical pharmacist and project manager? Are these personnel involved in pharmaceutical detailing activities for any pharmaceutical company?
    expertise area:
    expertise area:
    expertise area:
12. Are resume/s included for the project manager and clinical pharmacist with the bid?
13. Were a minimum of three references provided? Was client name, contact name, title, telephone number, contract type, size and duration provided? Was at least one of them from a state Medicaid Agency or other government program?
14. Does the bid demonstrate the ability to avoid real or perceived conflicts of interest?
15. Does the bid demonstrate the ability to perform duties as outlined in the ITB?

Attachment D

Medicaid Preferred Drug List

The various PDL Lists may be found on the Alabama Medicaid Agency web site at www.medicaid.alabama.gov

Attachment E

ALABAMA MEDICAID AGENCY
PREFERRED DRUG PROGRAM
PHARMACY AND THERAPEUTICS COMMITTEE
OPERATING PROCEDURES
Updated: December 2007

As defined by Alabama Code §22-6-122, the Medicaid Pharmacy and Therapeutics (P&T) Committee shall review and may recommend drugs or classes of drugs (drug class as defined by the American Hospital Formulary Service or AHFS classification system) to the Alabama Medicaid Agency for inclusion in the Medicaid Preferred Drug Program. Drugs will be reviewed according to the AHFS classification. Each therapeutic class review will contain agents that share the same first six digits of the AHFS product code and are active on the Alabama Medicaid drug file. Combination products that share similar Food and Drug Administration (FDA) approved indications as other drugs within that AHFS class may be reviewed with the single entity agents from within that same AHFS class.

The P&T Committee must develop its preferred drug list recommendations by considering the clinical efficacy and safety of a product. Generics and over the counter (OTC) drugs covered by Medicaid may be considered preferred drugs without appearing on the preferred drug list. The P&T Committee will consider recommending preferred status for brand products only. However, the P&T Committee has the ability to recommend generic products be removed from preferred status.

For the purposes of P&T reviews and manufacturer reconsiderations, the recommendations of the Medicaid P&T Committee must be based on sound clinical evidence found in labeling, drug compendia and published peer reviewed clinical literature pertaining to the use of the drug. Poster board presentation/abstracts cannot be included for the review of the class or drug if no full study has been conducted and published in peer reviewed literature. Also while agents within this therapeutic class may have demonstrated positive activity via in vitro trials, the clinical significance of this activity remains unknown until fully demonstrated in well-controlled, peer-reviewed in vivo clinical trials. As such, class/product reviews and the recommendations provided are based exclusively upon the results of such clinical trials.
Therefore, in vitro studies will not be included for the review of the class or drug.

Public Notice

Medicaid will provide notice to the public of Pharmacy and Therapeutics (P&T) Committee meetings and agenda items not less than (30) calendar days in advance of scheduled meetings. The notice will be provided via the Medicaid web site.

Medicaid will send written notification not less than (30) calendar days prior to a meeting of the P&T Committee to pharmaceutical manufacturers whose brand name drug(s) may be considered for preferred status at said meeting. This notice will be provided via US Certified Mail and the Medicaid web site. If an issue arises during a clinical review conducted by the P&T Committee that requires follow-up consideration at the next P&T Committee meeting, a minimum of thirty (30) days notice will be given to affected manufacturers.

Medicaid will maintain a database of industry representatives for the purpose of correspondence and notice regarding the Preferred Drug Program. It is the responsibility of the manufacturer to provide accurate contact information to the Medicaid Pharmacy Director delegated representative and to provide update information as needed. Contact information is to be provided on the Pharmaceutical Manufacturer Contact Information Form located on the Medicaid web site. It is also available from the Medicaid Pharmacy Program Office at (334) 242-5050. In the event no contact information is provided to Medicaid, the Legal Contact on file with the Medicaid Drug Rebate Program will be utilized for notices.

Request For Product Review

Manufacturers may request a product review for a new pharmaceutical product falling within the scope of the Preferred Drug Program. A new product is defined as any new drug entity, including combination products, that has not been previously commercially available.

If a product that is currently commercially available has a new dosage form, it is not considered a new product and would not be eligible for a new product review before the P&T Committee. These products would be included the review of the entire AHFS class unless there is a new indication for the product.

a. Requests for product reviews must be submitted in writing and directed to the Medicaid Pharmacy Director or delegated representative.

b. Requests for product reviews of drugs will be considered in the order in which they are received unless Medicaid identifies a need to place a higher priority on a particular class/drug.

c. A product or a product with a new indication must have been on the market for a minimum of 180 days prior to a request for product review.

Manufacturers may submit written evidence supporting inclusion of a product on the Preferred Drug List to the Medicaid Pharmacy Clinical Support Personnel or delegated representative and should be clearly labeled as a request for product review. This information may be submitted to Medicaid or its delegated representative at any time. However, the scheduling of the product's review will be at Medicaid's discretion.

Manufacturer Written Comments

Manufacturers have the opportunity to present comments to the Medicaid P&T Committee as required by Act No. 2003-297 through written comments directed to the Medicaid Pharmacy Director or delegated representative.

a. Comment period is for a period of 21 calendar days prior to the Pharmacy and Therapeutics Committee meeting. It is the responsibility of the manufacturer to verify receipt by Medicaid or its designee. If the deadline falls on a business day, the summary

must be received by 5:00 p.m. Central Time (CT). If the deadline falls on a weekend or holiday, comments must be received by noon CT of the next business day.

b. Manufacturer comments will be restricted to products that are being reviewed for preferred status.

c. All manufacturer comments received by the deadline must be approved to be included in the review packet provided to the P&T Committee members. Manufacturer comments **must** meet the following criteria:
   1. be limited to clinical information only,
   2. be limited to evidence-based clinical information and to Food and Drug Administration (FDA)-approved indications covered under the Alabama Medicaid Pharmacy benefit,
   3. exclude any reference to cost,
   4. exclude anecdotal content , and
   5. exclude general drug or disease specific economic information.

   Any comments found to contain references to cost/economic and/or anecdotal information will be rejected in their entirety.

d. Manufacturer comments should be clearly labeled as such and should indicate the product and drug class the comments represent. It is the responsibility of the manufacturer to provide twenty (20) copies of the written comments by the deadline.

e. Manufacturer comment submissions should be limited to one drug product per packet. Manufacturers wanting to provide written comments on more than one drug product must submit a separate packet for each product.

f. Manufacturer comment submissions are limited to 100 pages single-sided (or 50 pages double sided) and a maximum binder size of 1 inch.

g. Manufacturer written comment submissions are limited to hard copy written form only, not CD-Rom or email, etc.

h. Manufacturers will receive formal written communication from the Medicaid Pharmacy Director or delegated representative alerting them if the written comments have been accepted or rejected.

i. All manufacturer comment submissions must meet all criteria, received by the stated deadline and be approved Medicaid or its designee to be included in the review packet. Failure to abide by all of these requirements upon submission will result in a rejection of the clinical comments in their entirety. Manufacturers are also encouraged to submit information as soon as possible. Waiting until just days prior to the deadline for submission of these materials may not allow time for corrections and resubmission prior to the deadline. No submissions or resubmissions will be accepted after the designated deadline.

Manufacturer Oral Presentations

Manufacturers have the opportunity to make oral presentations to the Medicaid P&T Committee as required by Act No. 2003-297 through a brief oral summary of their product. Oral Presentations will be restricted to products that are being reviewed for preferred status.

1. Oral Presentation Summary

a. Written submission of a one page summary (1 copy, single-sided) of the material to be presented at the P&T meeting must be received by the Medicaid Pharmacy Director or delegated representative a minimum of 21 calendar days prior to the scheduled P&T meeting. It is the responsibility of the manufacturer to verify receipt by Medicaid or its designee. If the deadline falls on a business day, the summary must be received by 5:00 p.m. CT. If the deadline falls on a weekend or holiday, the summary must be received by noon CT of the next business day.

b. The summary must include all major points to be made during the presentation and a complete summary of the information to be shared at the meeting. This document including any references must be included on a single side of the document. The summary may not include references, package inserts or any other information on the reverse side of the document. Copies, provided by Medicaid, will be distributed to the P&T Committee members at the time of the meeting.

c. The oral presentation summary should be clearly labeled as "Oral Presentation Summary". Submissions are limited to hard copy written form only, not CD-Rom or email, etc. Manufacturer comments **must** meet the following criteria:
    1. be limited to clinical information only,
    2. be limited to evidence-based clinical information and to Food and Drug Administration (FDA)-approved indications covered under the Alabama Medicaid Pharmacy benefit,
    3. exclude any reference to cost,
    4. exclude anecdotal content,
    5. exclude general drug or disease specific economic information, and
    6. reference statistical information.

    Any comments found to contain references to cost/economic and/or anecdotal information will be rejected in their entirety.

d. The oral presentation summary should be limited to one drug product per submission. Manufacturers wanting to provide an oral presentation on more than one drug product must submit a separate one-page summary for each product.

e. All statistics identified for discussion must be supported by noting the source from which the information was obtained. This information does not have to be in formal reference form.

f. Manufacturers will receive formal written communication from the Medicaid Pharmacy Director or delegated representative alerting them if the oral presentation summary has been accepted or rejected.

g. All oral presentation summary submissions must meet all criteria, received by the stated deadline and be approved Medicaid or its designee to be included in the review packet. Failure to abide by all of these requirements upon submission will result in a rejection of the oral presentation summaries in their entirety. Manufacturers are also encouraged to submit information as soon as possible. Waiting until just days prior to the deadline for submission of these materials may not allow time for corrections and resubmission prior to the deadline. No submissions or resubmissions will be accepted after the designated deadline.

2. Oral Presentations

a. Oral presentations will be restricted to products that are being reviewed for preferred status.

b. Presentations will be limited to a maximum of five (5) minutes per representative per drug product. Each drug product will be treated as a separate presentation. In the event a manufacturer has more than one drug product in a drug class, each drug product is allowed a five (5) minute presentation. The same representative may perform the separate presentations in a drug class.

c. Presentations will be limited to one representative per product. Only one presentation per product will be permitted.

d. Presenters must register with Medicaid at P&T meetings a minimum of ten (10) minutes prior to the scheduled start time of the meeting. A sign-in sheet will be provided at a registration table at the meeting location. Those not registered by the designated cut off time will not be allowed to make presentations. It is the sole responsibility of the manufacturer to ensure that the presenter has signed in by the designated timeframe.

e. Representatives will be called to present in the order in which they signed in by drug class. At the initiation of the 5 minute presentation, the speaker will be required to state any financial interest in or other relationship with the manufacturer of any of the product(s) the speaker intends to discuss.

f. The Chairman will call for presentations by drug class. The oral presentation period will immediately precede the clinical review of each drug class. Medicaid's Contractor will then present clinical reviews by class. All questions regarding specific products and/or AHFS drug classes will be answered by the clinical contractor after the clinical review of the class.

g. Presentations must be limited to verbal comments. No visual aids other than the designated handouts are permitted.

h. Presentations must be limited to comments regarding the branded products within the class being considered for preferred status at the current meeting.

i. Presentations are to be limited to clinical issues approved in the single sided oral presentation summary. Presenters will be stopped if information other than the approved oral presentation summary is presented. Oral presentations should follow the one page summary that was submitted to Medicaid.

j. Oral Presentations will be allowed subject to time constraints at the discretion of the Chairman or the Medicaid Commissioner so that the P&T Committee's ability to complete the planned agenda is not impeded.

Meeting Attendance

Attendees of meetings are to limit distractions to a strict minimum. Cellular telephones, pagers and other media devices must be turned off or to silent mode before entering the meeting room.

All attendees of the P&T Committee meetings are to sign-in at the registration table.

Public Information

P&T Committee review packet will be posted to the Medicaid web site by close of business the day prior to the P&T meeting. The review packet will not be available for distribution or purchase at the sign-in table.

Medicaid shall post the PDL decisions to the Medicaid web site on the 10th business day following the date of the P&T Committee meeting.

Medicaid shall post the meeting minutes to the Medicaid website within 45 days following the date of the P&T Committee meeting.

Notice of prior authorization will be posted to the Medicaid web site a minimum of two weeks prior to the implementation of the PA. In addition, the prior authorization request form and criteria updates (or their location on the website) will also be posted with this notice.

Reconsideration Process

Manufacturers may request a reconsideration of a clinical recommendation of the P&T Committee if there is new clinical evidence-based, peer reviewed information to consider that was not presented during the P&T review. A written request must be submitted to the Medicaid Pharmacy Director or designated representative and must be received within thirty (30) calendar days of the posting of the PDL decisions to the Medicaid web site.

A request must include two (2) copies of a letter requesting reconsideration of a clinical recommendation and clinical documentation as described in the policy including references to

justify reconsideration. Manufacturer contact information must also be included with the submission.

Medicaid will respond in writing to all appeals within ninety (90) calendar days of receipt. Responses will be sent via US Mail.

General

Medicaid staff reserves the right to delete agenda items if deemed necessary due to time constraints of the meeting.

General information, requests or questions regarding P&T/PDL should be directed to Alabama Medicaid P&T designated contact person unless otherwise stated.

This policy is posted on Alabama Medicaid's website as the Pharmacy and Therapeutic Committee's Operating Procedures.

P&T/PDL CONTACT INFORMATION:

Alabama Medicaid Agency
Bakeba R. Thomas, Administrator
Pharmacy Clinical Support Unit
501 Dexter Avenue
P. O. Box 5624
Montgomery, AL 36103-5624

Telephone: (334) 242-5050
Fax: (334) 353-7014
Email: Bakeba.Thomas@medicaid.alabama.gov
Medicaid web site: www.medicaid.alabama.gov

Attachment F

Examples of previous clinical reviews presented to the Pharmacy and Therapeutics Committee may be found on the Alabama Medicaid Agency web site at www.medicaid.alabama.gov

Attachment G

POLICY AND PROCEDURES FOR MEETING WITH PHARMACEUTICAL MANUFACTURERS

In the spirit of fairness, consistency and integrity, the following policy and procedures will apply to all meetings between Medicaid and representatives of the pharmaceutical industry (hereafter referred to as PI reps):

1. All meetings between Medicaid and PI reps must be scheduled in advance. PI reps making cold calls to the Medicaid office will not be given a forum.

2. Priorities on meeting dates between Medicaid and PI reps will be determined by the agenda and priorities of the Alabama Medicaid Agency.

3. All meetings must be requested in writing. All requests should include the purpose for the meeting as well as contact information for the requestor. Requests may be sent via email, FAX or US Mail.

4. Upon receipt of a request for a meeting, Medicaid will make a determination of appropriate action. If Medicaid determines that the request can be handled without a meeting, the PI rep will be notified. If Medicaid determines that a meeting is required, the PI rep will be contacted for scheduling.

5. Medicaid will not grant meetings to PI reps for the purpose of introductions. Scheduled DUR Board and P&T Committee meetings are open to the public and are the ideal time to meet Medicaid staff.

6. Medicaid will not grant meetings to PI reps for the purpose of product presentations. If there is a valid concern regarding Medicaid policy governing a product, information detailing the concern/issue should be submitted in writing to the Medicaid Pharmacy Program Manager.

7. Only submitted and approved agenda items may be discussed during a meeting between Medicaid and PI reps. If further unrelated issues are identified during a meeting, a separate meeting will need to be requested.

8. The pharmaceutical industry is expected to limit to two (2), the number of PI reps to meet with Medicaid unless Medicaid has granted approval in advance.

9. The breakfast, lunch and dinner period is excluded as a meeting time and forum.

10. This policy applies to all meetings involving the Medicaid Pharmacy Program staff and Medicaid clinical staff to include meetings pertaining to Pharmacy Program issues, product discussions, disease management opportunities and Preferred Drug Program negotiations.

11. Requests for meetings should be directed as follows:

Bakeba R. Thomas, Pharmacy Clinical Support Unit Administrator
Email: Bakeba.Thomas@medicaid.alabama.gov or FAX: (334) 353-7014

Lynn Abrell, Drug Rebate Unit
Email: Lynn. Abrell@medicaid.alabama.gov or FAX: (334) 353-7014

Attachment H

Covered Drug Listings

The Maximum Unit List, Nutritional lists (List C and A) and various PDL Lists may be found on the Alabama Medicaid Agency web site at www.medicaid.alabama.gov

Attachment I

Hemophilia Management Standards of Care

In order to be paid for providing blood clotting factor to Alabama Medicaid recipients, the provider must agree to provide, at the minimum, the following clinically appropriate items and services to their hemophilia patients:

(1) Home or office delivery of blood clotting factor and supplies. All shipments/delivery of clotting factor, including overnight deliveries, must use appropriate cold chain management and packaging practices to ensure proper temperature, drug stability, integrity, and efficacy are maintained during shipment.

(2) Educational materials and programs.

(a) The provider shall develop a training library at each enrolled provider location with materials for patient use, to include but not limited to, audio, video, electronic, and written materials.

(b) The provider shall offer educational materials to patient or family/caregiver at minimum at initiation of participation with the provider, yearly during the in-home assessment, and upon the request of Medicaid, the prescribing physician, or patient or family/caregiver.

(c) Topics of education shall include, but not be limited to, specific patient and family/caregiver education aimed at preventing injury that would result in a bleed, self-administration and reconstitution of blood clotting products.

(3) Medically necessary ancillary supplies required to perform the actual IV administration of clotting factor. Supplies may be billed to Medicaid through the Durable Medical Equipment (DME) program. In addition, sharps containers and any other necessary biohazardous waste containers shall be provided, as well as pickup and disposal of waste containers according to national, state and local biohazardous waste ordinances.

(4) Emergency telephone support 24 hours a day, 7 days a week to ensure patients are directed appropriately for care in emergent situations.

(5) For the purposes of this Rule and the Alabama Medicaid Agency hemophilia management standards of care, "clinical staff trained in hemophilia and related blood clotting factor related diseases" is defined as follows:

(a) Pharmacists are required to obtain a minimum of two (2) Continuing Education (CE) credit hours per year that are specific to hemophilia or related blood clotting factor-related diseases.

(b) Nurses and social workers are required to obtain a minimum of 4 Continuing Education (CEU) hours per year (8 hours every 2 years) that are specific to hemophilia or related blood clotting factor-related diseases.

Continuing education must be specific to hemophilia or related blood clotting factor-related diseases and recognized by a state or national hemophilia or bleeding disorder

education/support group (for example: Hemophilia Federation of America or the National Hemophilia Association).

(6) Emergency delivery of blood clotting factor within 24 (with a target of less than 12) hours of the receipt of a prescription for a covered person's emergent situation, or notification of the patient with an existing valid prescription. Emphasis should be placed during patient education of the importance of keeping an adequate supply on hand and self-administration for emergent situations.

(7) A pharmacist, nurse, and/or a case representative assigned to each patient. A case representative shall maintain, at a minimum, monthly telephone contact with the patient or family/caregiver to include, but not limited to:

-Inquiry regarding patient's current state of well-being
-Assessment of patient/family compliance/adherence, and persistence with the medical treatment plan
-Incidence of adverse events
-Incidences of supply or equipment malfunctions
-Home inventory check of factor and supplies
-Confirmation of next delivery date

Case representatives may include administrative support staff, but must coordinate with clinical staff (as described in (5) above) in the event a clinical issue should arise.

(8) Compliance programs.

(a) The provider must assess patient adherence on monthly telephone contact (see (7) above) and on all in-home visits by a pharmacist, nurse, or case manager.

(b) The provider must verify the amount of clotting factor the patient has on hand prior to each dispense. Blood clotting factor and related products are not to be sent to the patient on an auto-ship basis. The provider shall discourage "stockpiling" of product.

(c) The number of bleeds and infusions from the prior shipment shall be tracked to validate the need for additional product or non-compliance with the medical treatment plan.

(9) Notification of product recalls or withdrawals.

(a) Any stock of recalled medications/equipment/supplies shall be removed from stock and quarantined immediately.

(b) Any recalled items dispensed to patients shall be retrieved and quarantined; notification to patients must occur within 24 hours of the recall receipt.

(c) The prescribing physician shall be notified of a medication recall. A prescription for an equivalent product shall be obtained, if necessary.

(10) Visiting clinical services.

(a) At minimum, an initial and subsequent yearly in-home assessment of the patient, family/caregiver, and environment shall be conducted by a nurse or pharmacist trained in blood clotting factor related diseases.

(b) Additional in-home assessments of the patient, family/caregiver, and environment deemed necessary by the physician or patient situation shall be conducted.

(c) Visits may be provided directly by the provider or by arrangement with a qualified local home health care agency. All hemophilia-related clinical staff must be trained in hemophilia and bleeding disorder related diseases.

(11) A registered pharmacist trained in blood clotting factor related diseases to perform assay to prescription management. Variance in assay to prescription/target dose should not exceed +/- 10%.

(12) Adverse drug reaction and drug interaction monitoring and reporting.

(a) Pharmacists shall counsel the patient or family/caregiver in accordance with the Omnibus Budget Reconciliation Act of 1990 (OBRA 90) to encourage appropriate medication use, promote realistic therapy expectations, help recipients manage or minimize expected adverse effects and encourage compliance.

(b) Pharmacists shall report any issues or concerns related to the patient's medications to the physician. For significant events, utilization of the FDA 3500 MedWatch voluntary reporting form is encouraged.

(13) Continuation of Care. The provider shall not present any bill to or collect any monies from a covered Medicaid recipient with whom the provider has agreed to the provision of services and supplies for the home treatment of bleeding episodes associated with hemophilia, except as follows:

(a) to collect the copayments/coinsurance amounts the covered person is required to pay under the terms defined by Medicaid, or

(b) if the service/product has been deemed "non-covered" and the recipient has been notified in advance as outlined in the Alabama Medicaid Agency Administrative Code and Provider Billing Manual.

Upon discontinuation of services by the provider, the provider shall, at a minimum, coordinate for another designated health care provider to provide services to covered persons, prior to withdrawal of any hemophilia-related services from the home of any covered person. The provider shall continue to provide services and supplies to a covered individual until the individual obtains an alternate source of services and supplies. Every effort shall be made by the provider (including notification to the Medicaid Director of Pharmacy) to find an alternative provider to ensure that the coordination of care/transition follows the minimum standards of care as set forth in this document.

(14) The Alabama Medicaid Agency (or its designated representative), to ensure clinically appropriate services are being given to hemophilia patients, shall monitor providers of blood clotting factor by prospective and retrospective audits, as well as administer a patient/family/caregiver satisfaction survey to include, but not limited to, measurement of:

(a) staff availability
(b) staff knowledge
(c) timeliness of deliveries
(d) accuracy of supplies and equipment
(e) overall satisfaction

If a provider does not meet one or more of the standards for care, as outlined in this Rule, the Alabama Medicaid Agency shall provide a written notice of that determination, with an explanation therefore, to the provider. The provider will not be reimbursed for blood clotting factor or hemophilia related services until the provider meets the standards as approved by the Agency.